

**Use of the Internet for the delivery and  
evaluation of interventions aimed at reducing  
alcohol consumption**

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## Declaration

I, Zarnie Claire Selina Khadjesari confirm that the work presented in this thesis is my own.

Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

## Abstract

Alcohol is the most harmful drug in the UK, with harm extending beyond the individual to affect other people, society and the economy. Interventions effective at reducing alcohol intake are hindered by barriers to delivery. This thesis aimed to explore the use of the Internet for the delivery and evaluation of interventions for reducing alcohol intake, with a view to widening the availability of services. The effectiveness of stand-alone computer-based interventions was determined in the first systematic review in this field to present clinically meaningful outcomes, i.e. grams per week and binge frequency (Chapter 2). A number of limitations of the literature were identified, most of which were subsequently addressed in the Down Your Drink (DYD) online trial. This online trial of an Internet-based intervention provided the context for the exploration of methodological challenges introduced by the Internet setting (Chapter 3). Conventional measures of alcohol intake may not retain their validity when transferred online. An online measure of past-week alcohol consumption was created and validated for use as the primary outcome measure in the DYD trial (Chapter 4). Low rates of follow-up are common in online trials and increase the possibility of bias. Two sequential online trials found low value incentives (e.g. £5) did not improve follow-up in the DYD trial, whereas higher value incentives (e.g. £10) were effective and more cost-effective (Chapter 5). Qualitative interviews with DYD trial participants provided a unique insight into the experiences of a previously unstudied group of hazardous drinkers seeking help online (Chapter 6). The Internet setting was found to mitigate some of the barriers to seeking help in-person, attracting a large group of 'e-help-seekers' whose varied needs are unmet by existing services. The implications of these findings on the development of online services were discussed along with directions for future research.

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## Abbreviations

%ABV	% Alcohol By Volume
AC	Active comparator group
ADS	Alcohol Dependence Scale
APQ	Alcohol Problems Questionnaire
AUDIT	Alcohol Use Disorders Identification Test
BAL / BAC	Blood Alcohol Level / Blood Alcohol Concentration
CBT	Cognitive Behavioural Therapy
cCBT	Computerised Cognitive Behavioural Therapy
CORE-OM	Clinical Outcomes in Routine Evaluation –Outcome Measure
DYD	Down Your Drink
eSBI	Electronic Screening and Brief Intervention
G	Grams
GP	General Practitioner
L	Litre
LDQ	Leeds Dependence Questionnaire
MAC	Minimally active comparator group
MET	Motivational Enhancement Therapy
MI	Motivational Interviewing
MRC NPRI	Medical Research Council National Prevention Research Initiative
NICE	National Institute for Health and Clinical Excellence
RAPI	Rutgers Alcohol Problem Index
RCT	Randomised Controlled Trial
SD	Standard deviation
SMD	Standardised mean difference

TOT-AL	TOTal past-week ALcohol consumption measure
UCL	University College London
UK	United Kingdom
UKATT	UK Alcohol Treatment Trial
US	United States of America
WHO	World Health Organisation

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## Disclosure

This thesis consists of a series of empirical studies around the use of the Internet for delivering and evaluating interventions for reducing alcohol intake. These studies include a systematic review of computer-based interventions for reducing alcohol intake (Chapter 2), development and validation of an online measure of alcohol consumption (Chapter 4), two online trials of the impact of incentives on improving follow-up in an online trial (Chapter 5), and a qualitative study of people's experience of seeking help online, using an Internet-based intervention and taking part in an online trial (Chapter 6). I conducted all aspects of these studies including protocol development, application for ethical approval, data collection, analysis and interpretation of findings. Where additional help was required, this is indicated in the thesis.

The Down Your Drink trial (DYD; presented in Chapter 3) provided the context for this research, as an online trial of an Internet-based alcohol misuse intervention. An in-depth description of the trial is provided in Chapter 3 to aid interpretation of the studies in the subsequent chapters, but the DYD trial itself does not constitute an empirical contribution to this thesis. The DYD trial was designed, conducted, analysed and interpreted by a multidisciplinary team of general practitioners, addiction specialists, psychologists, health economist, statisticians and computer programmers (see Acknowledgements). As the research fellow on this trial, I was involved in developing the DYD intervention (Linke et al. 2008), optimising the trial parameters (Murray et al. 2009) (which led to the studies in Chapters 4 and 5) and facilitating the mechanics of the trial.

## Publications related to this thesis

The following publications have resulted from the research conducted for this thesis and the Down Your Drink trial (the first three publications are provided in Appendix 1).

Khadjesari, Z., Murray, E., Hewitt, C., Hartley, S., & Godfrey, C. 2011a, 'Can stand-alone computer-based interventions reduce alcohol consumption? A systematic review', *Addiction*, vol. 106, no. 2, p. 267-82.

Khadjesari, Z., Murray, E., Kalaitzaki, E., White, I. R., McCambridge, J., Godfrey, C., & Wallace, P. 2009, 'Test-retest reliability of an online measure of past-week alcohol consumption (the TOT-AL), and comparison with face-to-face interview', *Addictive Behaviors*, vol. 34, no. 4, p. 337-42.

Khadjesari, Z., Murray, E., Kalaitzaki, E., White, I. R., McCambridge, J., Thompson, S. G., Wallace, P., & Godfrey, C. 2011b, 'Impact and costs of incentives to reduce attrition in online trials: two randomized controlled trials', *Journal of Medical Internet Research*, vol. 13, no. 1, p. e26.

Cunningham, J. A., Khadjesari, Z., Bewick, B. M., & Riper, H. 2010, 'Internet-based interventions for problem drinkers: From efficacy trials to implementation', *Drug and Alcohol Review*, vol. 29, no. 6, p. 617-22.

Linke, S., McCambridge, J., Khadjesari, Z., Wallace, P., & Murray, E. 2008, 'Development of a psychologically enhanced interactive online intervention for hazardous drinking', *Alcohol and Alcoholism*, vol. 43, no. 6, p. 669-74.

McCambridge, J., Kalaitzaki, E., White, I. R., Khadjesari, Z., Murray, E., Linke, S., Thompson, S. G., Godfrey, C., & Wallace, P. 2011, 'Can differences in the length or relevance of questionnaires impact upon attrition in online trials? A randomised controlled trial', *Journal of Medical Internet Research*, vol. 13, no. 4, p. e96.

McCambridge, J., O'Donnell, O., Godfrey, C., Khadjesari, Z., Linke, S., Murray, E., & Wallace, P. 2010, 'How big is the elephant in the room? Estimated and actual IT costs in an online behaviour change trial', *BMC Research Notes*, vol. 3, p. 172.

Murray, E., Khadjesari, Z., White, I. R., Kalaitzaki, E., Godfrey, C., McCambridge, J., Thompson, S. G., & Wallace, P. 2009, 'Methodological challenges in online trials', *Journal of Medical Internet Research*, vol. 11, no. 1, p. e9.

Murray, E., McCambridge, J., Khadjesari, Z., White, I. R., Thompson, S. G., Godfrey, C., Linke, S., & Wallace, P. 2007, 'The DYD-RCT protocol: an on-line randomised controlled trial of an interactive computer-based intervention compared with a standard information website to reduce alcohol consumption among hazardous drinkers', *BMC Public Health*, vol. 7, p. 306.

Wallace, P., Murray, E., McCambridge, J., Khadjesari, Z., White, I. R., Thompson, S. G., Kalaitzaki, E., Godfrey, C., & Linke, S. 2011, 'On-line Randomized Controlled Trial of an Internet Based Psychologically Enhanced Intervention for People with Hazardous Alcohol Consumption', *PLoS One.*, vol. 6, no. 3, p. e14740.



## Chapter 1: Background to thesis

### ***Chapter overview***

The use of the Internet for delivering interventions for reducing alcohol intake may broaden the availability of services and overcome some of the barriers to accessing help in-person. This may help narrow the gap that exists between need and access to help. This thesis considered the effectiveness of Internet-based interventions and the experiences of their users. It also explored the innovative role of the Internet in evaluating these interventions in their naturalistic setting, by considering the methodological challenges of conducting online trials, with a view to improving the methodological rigour of this emerging field. The aim of this chapter is to provide the background and rationale for this thesis topic.

This chapter begins by outlining why alcohol misuse is a problem. It provides a broad overview of alcohol-related harm, the different types of alcohol misuse and harmful patterns of drinking, and the prevalence of alcohol misuse in England. A brief description of effective interventions for reducing alcohol intake is then necessary as they form the basis for interventions delivered over the Internet. Barriers to implementing brief interventions in-person lead to the introduction of the Internet as an alternative means of delivery, with its potential advantages of reach and anonymity. The thesis aims, objectives and structure are introduced at the end of this chapter. While this chapter provides the necessary background to this thesis, the following chapters provide a more in-depth, subject-specific context for each study.

## ***The impact of alcohol-related harm***

Alcohol misuse is among the leading causes of preventable death worldwide. In 2004, alcohol accounted for 3.8% of global mortality (6.3% for men, 1.1% for women), which equates to over 2.2 million deaths (Rehm et al. 2009). The highest mortality rates were found in the European region, with alcohol causing 1 in 10 deaths in men. Most alcohol-related deaths were attributable to unintentional injuries, followed by cardiovascular diseases, cancer, cirrhosis of the liver, intentional injuries and neuropsychiatric disorders (Rehm et al. 2009). Over the last decade, Britain has seen the greatest increase in mortality from cirrhosis of the liver in Western Europe (Leon & McCambridge 2006), whilst other European countries have seen a decline or remained stable (Sheron et al. 2011). In Europe, only smoking and hypertension precede alcohol as the largest risk factor for ill-health (Anderson & Baumberg 2006; World Health Organisation 2002), with alcohol accounting for 4.6% of the global burden of disease and injury in 2004 (7.6% for men, 1.4% for women) (Rehm et al. 2009). Chronic health problems associated with alcohol intake include neuropsychiatric disorders (such as depression), cirrhosis of the liver, cardiovascular diseases, cancer, and maternal and perinatal disorders (e.g. low birth weight) (Rehm et al. 2009).

Alcohol-related harm reaches beyond the individual drinker to affect other people, society and the economy, making it the most harmful drug in the United Kingdom (Nutt et al. 2010). In 2006, there were over 7,000 injuries and 560 deaths from road accidents caused by alcohol (excluding the drink-driver) (Department of Health 2009). In England, marriages are twice as likely to result in divorce if one or both partners have an alcohol problem. Children are more likely to experience behavioural and emotional problems and underperform at school if their parents are problem drinkers (Department of Health 2009). Alcohol-related harm caused to others also includes foetal alcohol spectrum disorder, family deprivation, domestic violence, marital problems, suicide, homelessness, and

sexually transmitted diseases through risky sexual behaviour (Anderson et al. 2009; Prime Minister's Strategy Unit 2004). The impact of alcohol-related harm on society includes crime, anti-social behaviour, violence, vandalism (e.g. to cars, public transport, public places), homicide, sexual assault and child abuse (Anderson et al. 2009; Prime Minister's Strategy Unit 2004). In England, over 8,000 police officers a year and half of all emergency department staff are assaulted in alcohol-related incidences (Department of Health 2009). The economy suffers through lost productivity at work, including days lost due to alcohol-related sickness (11-17 million days annually) and reduced employment (15-20 million days annually) (Anderson et al. 2009; Prime Minister's Strategy Unit 2004).

Alcohol misuse is a financial burden on the health service and wider economy, with an estimated cost of €125 billion a year in Europe and £20 billion a year in England (Anderson & Baumberg 2006; DH / National Treatment Agency for Substance Misuse 2005). These costs encompass the harm caused to the individual, other people, society and the economy (as detailed above). Alcohol-related harm is thought to have cost the National Health Service in England £2.7 billion in 2006/7 prices. This estimate includes several factors such as hospital inpatient, outpatient, and accident and emergency visits (Department of Health 2008). It has been suggested that for every £1 spent, a saving of £5 could be made through implementation of evidenced-based treatment for alcohol misuse (DH / National Treatment Agency for Substance Misuse 2005; UKATT Research Team 2005a).

### ***Types of alcohol use, misuse and prevalence***

Alcohol misuse refers to consumption that exceeds recommended safe limits. In Britain, sensible drinking limits use units of alcohol to provide an operational public health message (Royal Colleges 1995). A unit of alcohol is calculated by multiplying the volume

(ml) of the drink by the percentage of 'alcohol by volume' (%ABV - % of pure alcohol within the drink), then dividing by 1000. The sensible drinking guidelines were originally presented as weekly limits, but were later changed to daily limits, purportedly to account for the harm caused by binge drinking (Prime Minister's Strategy Unit 2004). This move to daily limits has been criticised for increasing the amount of alcohol an individual can safely consume within in a week (50% rise for women, 33% rise for men; outlined below), contrary to expert advice (Edwards 1996; Marmot 1995).

- Weekly limit: up to 14 units per week (women); 21 units per week (men) (Department of Health 1992; Royal Colleges 1995).
- Daily limit: up to 2-3 units per day (women); 3-4 units per day (men) (Inter-Departmental Working Group 1995).

People drinking within these safe limits have been classified as 'lower risk' drinkers, whereas those drinking above these limits (up to 35 ♀ / 50 ♂ units per week) are considered 'increasing risk' drinkers (Department of Health 2008). When the sensible drinking limits were first issued, one unit of alcohol was equivalent to a glass of wine, half a pint of beer, and one shot of spirits. Since then, the average sized wine glass served in bars and pubs has increased from 125ml to 175ml, with many offering the larger 250ml glass (one third of a bottle of wine). A standard shot of spirits has also increased from 25ml to 35 ml in many outlets. In addition to vessel size, the strength of wine has increased over time. In the General Household Surveys (GHS) on alcohol use, the Office for National Statistics now assumes an average %ABV for wine of 12.5% (previously 9%) and asks respondents about glass size rather than assuming a volume of 125ml (Goddard 2007). This rise in the number of units contained within a standard drink and conflict between sensible drinking guidelines confuses the public health message (Ball et al. 2007) (see Chapter 6).

Alcohol misuse is a broad term that encompasses different types of drinkers. A number of ambiguous terms have been used to describe alcohol misusers, such as excessive or heavy drinkers or alcohol abusers. This thesis uses the terminology suggested by the World Health Organisation (Babor & Higgins-Biddle 2001), which divides alcohol misusers into three categories: hazardous drinkers are those at risk of (but not experiencing) alcohol-related harm; harmful drinkers are those experiencing alcohol-related harm, which could be physical, mental or social harm; dependent drinkers experience harm and show indication of alcohol dependence (relating to behavioural, cognitive and physiological functions) (Babor & Higgins-Biddle 2001). The boundaries between these categories are often blurred, and people are likely to move between them. However, categorising alcohol misusers in this way helps to determine a suitable treatment approach (Raistrick et al. 2006) (discussed below under Brief Interventions). There are two patterns of alcohol misuse that are thought to increase the likelihood of alcohol-related harm: chronic drinking and binge drinking.

- Chronic drinking (also termed as 'higher risk' drinking): consuming more than 35 ♀ / 50 ♂ units of alcohol a week (twice the weekly limit) (Department of Health 2008; Prime Minister's Strategy Unit 2004).
- Binge drinking (also referred to as heavy episodic drinking): consuming more than 6 ♀ / 8 ♂ units (twice the daily limit) on at least one occasion in the past week (Prime Minister's Strategy Unit 2004).

Chronic drinkers tend to be aged over 30 years and are more likely to suffer from alcohol-related ill-health, premature death and suicide (Prime Minister's Strategy Unit 2004).

Crimes committed by chronic drinkers are more likely to include domestic violence and drink-driving. Binge drinkers tend to be aged under 25 years; however, recently the largest proportion of male binge drinkers was in the 25-44 year age group (The NHS

Information Centre 2011). Binge drinkers are more at risk of accidents and poisoning, with men more likely to be the victims and perpetrators of violent offences (Prime Minister's Strategy Unit 2004).

On a global scale, Eastern Europe and Russia consume the largest amounts of alcohol in the world (15-25L alcohol per adult), followed by other parts of Europe including the UK (12-15L alcohol per adult) (Rehm et al. 2009). In 2007, around one quarter of adults (24%) aged 16 and above in England were drinking hazardously or harmfully (33% men and 16% women). A smaller proportion of alcohol misuse was attributed to dependent drinkers (6% of adults in England: 9% men and 3% women) (The NHS Information Centre 2009). In 2008, 22% of men and 15% of women were binge drinkers, and 7% of men and 5% of women were chronic drinkers (The NHS Information Centre 2010). 'White' men and women have the highest rates of hazardous drinking (36% men, 17% women), compared with 'Black' (19% men, 5% women) and 'South Asian' (12% men, 3% women) ethnicities. Similarly, alcohol dependence was more prevalent in 'White' men and women than other ethnicities (The NHS Information Centre 2009).

### ***Brief interventions and barriers to implementation***

Treatment for alcohol problems has traditionally focussed on dependent drinkers (Aasland et al. 2008). However, to reduce harm at a population level, efforts are needed to reduce consumption in the larger group of non-dependent drinkers rather than the smaller group of dependent drinkers. This phenomenon is known as the prevention paradox (Kreitman 1986; Rose 1981). The move towards a population strategy for alcohol misuse was instigated by a World Health Organisation Expert Committee in 1979, which called for an extension to the treatment base to reflect the range of needs (Aasland et al. 2008; World Health Organisation 1980). This call to broaden the range of intervention approaches for

alcohol misuse has been widely acknowledged (Institute of Medicine 1990; Prime Minister's Strategy Unit 2004; U.S.Preventive Services Task Force 2004; World Health Organisation 1980).

Brief interventions have met the call to broaden the base of intervention approaches and to address the gap between primary prevention and intensive treatment (Babor & Higgins-Biddle 2001). There is strong international evidence to support the use of brief interventions to reduce hazardous and harmful alcohol consumption, particularly in the primary care setting (Ballesteros et al. 2004; Beich et al. 2003; Bertholet et al. 2005; Bien et al. 1993; D'Onofrio & Degutis 2002; Kaner et al. 2007; Miller & Wilbourne 2002; Moyer et al. 2002; Poikolainen 1999; Whitlock et al. 2004). In England, brief interventions are recommended by the National Institute for Health and Clinical Excellence (NICE) as part of a tiered service for alcohol misusers (DH / National Treatment Agency for Substance Misuse 2006; NICE public health guidance 24 2010). Brief interventions encompass a range of preventive approaches that aim to reduce alcohol consumption to within recommended safe limits and consequently reduce or prevent alcohol-related harm. They are thought to increase motivation, or drive, to change behaviour, which is necessary in the non-help seeking individuals they are targeted towards (Boland et al. 2008). Although characteristically short, brief interventions may be simple (also known as minimal intervention or structured brief advice) or extended.

Simple brief interventions typically last between 5 and 15 minutes following a screening test for hazardous drinking (such as the AUDIT – Alcohol Use Disorders Identification Test (Babor et al. 2001)). They may include a number of components, such as personalised feedback on risk and harm associated with the current level of drinking, barriers to change, tips for cutting down and goal-setting (DH / National Treatment Agency for Substance Misuse 2006; NICE public health guidance 24 2010). This structured brief advice should

be based on the FRAMES approach, which is thought to illustrate the effective components of a brief intervention (Miller & Sanchez 1994). The acronym FRAMES stands for personalised Feedback on current levels of drinking, emphasis on the individual's personal Responsibility for change, Advice on what and how to change, a Menu of available treatments, Empathy as a therapeutic style, and enhancing Self-efficacy by expressing confidence in an individual's ability to change (Miller & Sanchez 1994). Miller and Sanchez acknowledge that an effective intervention may contain any combination of these elements. Simple brief interventions can be delivered by professionals not specialised in alcohol treatment and are delivered in general community settings such as primary care, emergency departments, higher education, the criminal justice system, or the workplace (Raistrick et al. 2006). Extended brief interventions may consist of several sessions that last for 20 to 30 minutes and are suited to people who need more than brief advice to reduce their drinking. They may be based on the principles of motivational interviewing, including motivational enhancement therapy (see Box 1 for further detail on these approaches). Although advocated for use in general, non-specialist settings, extended brief interventions should be delivered by trained professionals. Follow-up assessment is advised after the delivery of any brief intervention to assess its impact and, where necessary, to refer people onto more intensive treatment approaches (DH / National Treatment Agency for Substance Misuse 2006; NICE public health guidance 24 2010).



## Box 1. Theoretical approaches

### Personalised feedback

Personalised feedback, as detailed in FRAMES, is considered one of the key elements of an effective brief intervention to the extent that many brief interventions consist of this component alone. Personalised feedback can be delivered in many different forms, such as criterion feedback (also known as risk or problem-based feedback), which provides information on the risk or severity of the problem (e.g. you are drinking more than recommended safe limits); normative feedback, which compares individual data with that of a relevant reference group (e.g. you are drinking more than the majority of your peers); or ipsative feedback which uses a self-referent (e.g. you are drinking more this week than you did last week) (DiClemente et al. 2001). Personalised feedback may change behaviour in several ways. It may serve to educate the individual on potential risks and motivate behaviour change. It may work by challenging attitudes and beliefs about risk and benefits or by identifying barriers to change. Normative comparisons challenge social norms, which may result in behaviour change. Personalised feedback may also work by enhancing self-efficacy by demonstrating a particular skill set necessary for achieving change (DiClemente et al. 2001).

### Motivational Interviewing

Motivational Interviewing (MI) is typically concerned with enhancing motivation to change behaviour. It is a therapeutic approach characterised by an empathic, non-confrontational counselling style that supports the individual's self-efficacy (Miller & Rollnick 2002). It focuses on resolving ambivalence through developing a discrepancy between the problem behaviour, such as harmful drinking, and the individual's personal values. The MI approach is centred on the following principles: expressing empathy, developing discrepancy, rolling with resistance, supporting self-efficacy. There is substantial evidence

to support the MI approach with problem drinkers (Burke et al. 2003; Burke et al. 2004; Dunn et al. 2001; Miller & Wilbourne 2002; Vasilaki et al. 2006). The evidence comes from a range of interventions that use adaptations of the MI approach in both treatment seeking and non-treatment seeking populations.

### Motivational Enhancement Therapy

An adaptation of motivational interviewing commonly used with dependent drinkers is Motivational Enhancement Therapy (MET). In-line with MI, it aims to motivate change which then allows the individual to reduce their drinking independently. MET, as evaluated in a large US trial, consisted of four sessions that included personalised feedback in a motivational interviewing style, planning change, reinforcing progress, and encouraging reassessment (Miller et al. 1992). It was found to be as effective as Cognitive Behaviour Therapy (CBT) and 12-Step facilitation therapy at reducing alcohol intake (Project MATCH 1997). MET is also as effective as more intensive Social Behaviour and Network Therapy in the UK Alcohol Treatment Trial (UKATT Research Team 2005b). Its advocacy stems from its relative brevity compared with these other equally effective treatment approaches (UKATT Research Team 2001). Another example of an adapted motivational interviewing intervention, but for a less dependent population is BASICS (Brief Alcohol Screening and Intervention for College Students) (Dimeff et al. 1999). BASICS is an alcohol skills training programme that steers individuals away from risky drinking behaviours. It enhances an individual's motivation to change their drinking by employing motivational interviewing techniques. BASICS provides personalised feedback on risks associated with level of drinking, information on the effects of alcohol and if necessary provides cognitive and behavioural strategies for cutting down.

### Cognitive Behavioural Therapy

Cognitive behavioural therapy (CBT) is another therapeutic approach used to help people reduce their drinking. CBT is based on the concept of social–cognitive theory (Bandura 1986), where alcohol misuse is viewed as a behaviour learned through experience. The aim of therapy is to determine why alcohol is being consumed, the need it fulfils (e.g. reducing tension), and to find different ways of meeting those needs through skill development. Coping skills training helps people manage in high-risk situations that may lead to relapse. Intervention approaches may vary, for example in length, content and setting. CBT, as evaluated in ProjectMATCH, consisted of 12 sessions aimed at training people in behavioural or cognitive coping skills to manage their problems rather than using alcohol. Specific coping skills included: managing thoughts and cravings, awareness of negative thinking, relaxation skills, decision-making, problem-solving, and refusal techniques (Kadden et al. 1992). There is evidence to support the use of CBT at reducing alcohol consumption in dependent drinkers (Finney & Monahan 1996; Holder et al. 1991; Miller et al. 1995; Roth & Fonagy 1996), and effects are comparable to Motivational Enhancement Therapy or 12-Step facilitation therapy (Project MATCH 1997).

Brief interventions are targeted at non-help (or non-treatment) seekers, for example, patients opportunistically identified as drinking hazardously by a general practitioner in primary care (Raistrick et al. 2006). Treatment seekers, on the other hand, are generally in need of specialist alcohol treatment as they tend to exhibit more severe alcohol-related problems, such as symptoms of dependence, depression, anxiety over health and finances, loss of control, and negative life-events (Finney & Moos 1995; Hartnoll 1992; Tsogia et al. 2001). Treatment seekers are also more likely to demonstrate higher levels of motivation and readiness to change their drinking (Heather 1995). This is an important consideration when interpreting the impact of an intervention (Heather 1995) (see Chapters 2 and 3), as treatment seekers are more likely to benefit from the intervention

than non-treatment seekers (Apodaca & Miller 2003). These conventional concepts of treatment seekers and non-treatment seekers generally relate to the seeking of specialist, in-person treatment. People seeking help to reduce their drinking over the Internet appear to constitute a different group of help-seekers to those characterised above, as discussed in Chapters 6 and 7.

If implemented under ideal conditions, brief interventions could form a public health approach to reducing alcohol consumption (Heather 1996). However, there are several barriers to their delivery and a gap remains between need and access to treatment (Drummond et al. 2005; Drummond et al. 2011). Hazardous drinkers are rarely identified in primary care and so the opportunity for early identification and brief intervention is often missed (Cheeta et al. 2008; Denny et al. 2003; Seppa et al. 2004). Similar barriers to screening and brief intervention (SBI) are reported across the world. These include reluctance on the part of generic health professionals to engage in SBI due to time constraints, lack of training and support, lack of financial incentive, a fear of offending patients by discussing their alcohol consumption (Hutchings 2006; Johnson et al. 2011; McAvoy et al. 2001; Rapley et al. 2006; Wutzke et al. 1998), and a shortage of trained professionals capable of delivering extended brief interventions (Drummond et al. 2005).

### ***The Internet as an alternative mode of delivery***

Self-help resources address some of the barriers to delivering brief interventions by providing access to psychological treatment that does not involve contact with a therapist or health-care provider (Kypri & Cunningham 2008). Self-help resources are particularly advantageous for people not willing or not able to access help in-person. As with brief interventions delivered in-person, some self-help interventions are minimal and consist of personalised normative feedback (Agostinelli et al. 1995; Collins et al. 2002; Cunningham

et al. 2001; Sobell et al. 2002), while others use a more extensive range of techniques to promote behaviour change, such as those from Cognitive Behavioural Therapy and Motivational Interviewing (Cunningham et al. 2002; Heather et al. 1986; Heather et al. 1990; Kypri & Cunningham 2008; Raistrick et al. 2006; Sitharthan et al. 1996) (see Box 1). Self-help resources can be delivered in a variety of formats, such as paper-based books, manuals, leaflets, and via computers. Brief interventions delivered in-person provide a personalised encounter, yet are limited in their scalability; whereas printed self-help materials have greater scalability (they can be sent to an entire population at increased risk of harm), but are restricted by lack of individualisation (Abrams et al. 1996). The Internet provides a means of combining the scalability of a public health approach with the capacity to deliver a personalised intervention (Copeland & Martin 2004; Moyer et al. 2002). Internet-based, self-help interventions can be delivered at a population level and are intended to broaden the base of treatment available to alcohol misusers by extending the range of services (Kypri & Lee 2009).

Before presenting the potential advantages of Internet-based interventions for reducing alcohol consumption, it is important to clarify the terminology used in this thesis. The term 'Internet-based intervention' is used in this thesis to describe self-help resources delivered online, but it is an ambiguous term that has been used by researchers to describe several different types of online intervention. Internet-based interventions are distinct from online counselling and therapy, internet-operated therapeutic software, and other online activities, e.g. blogs, support groups, podcasts for accessing health information (Barak et al. 2009). Internet-based interventions have been classified into three different types: 1) web-based education interventions; 2) self-guided web-based therapeutic interventions; and 3) human-supported web-based therapeutic interventions (Barak et al. 2009). In line with these definitions, this thesis is interested in the use of self-guided (or non-guided, stand-alone) web-based therapeutic interventions (in essence, self-help interventions delivered

over the Internet). For simplicity, this thesis uses the term 'Internet-based intervention', or 'computer-based intervention' when the intervention is delivered by a computer, but not necessarily over the Internet.

A major advantage of delivering brief interventions over the Internet is scalability (or reach), which is vital for a public health intervention. In 2009, 76% of adults in the UK (37.4 million people) were accessing the Internet (Office for National statistics 2009) with a slightly lower proportion in Europe as a whole (52%), but with similar proportions in the US (74%) and Australia (80%) (Internet World Stats 2009). Of those people that use the Internet in Britain, 68% access information on health (Dutton et al. 2009). A general population survey in Ontario, Canada found 70% of alcohol misusers (n=312) have access to the Internet at home (Cunningham et al. 2006b). An Internet-based intervention can be accessed by a large number of people simultaneously and at any time of day or night, providing convenience and flexibility in the timing and length of exposure. Internet-based interventions are particularly beneficial where in-person services are limited or non-existent due to high demand (waiting-lists) or geographically remote areas (Finfgeld-Connett & Madsen 2008). The privacy and anonymity of the Internet is thought to be particularly important, with stigma and embarrassment known to impede formal (in-person) help-seeking for alcohol problems (Cunningham et al. 1993; Fortney et al. 2004; Jordan & Oei 1989; Roizen 1977). Internet-based interventions can be updated with immediate effect and have the capacity to deliver and retain large amounts of data. Information can be delivered in different formats, e.g. text, video, graphics, audio (Murray 2009). The interactive nature of the Internet means that information provided by the user can be used to deliver instantaneous personalised feedback (Copeland & Martin 2004; Elliott et al. 2008) – an essential component of brief interventions (Miller & Sanchez 1994). It has also been suggested that the empathic, non-confrontational counselling style that is characteristic of motivational interviewing can be translated to a web-based format through

the tone of text. The inclusion of interactive exercises enable the individual to reflect on their behaviour, with an emphasis on individual responsibility and choice for change (Linke et al. 2008). Another advantage is that the content of the intervention is delivered consistently and is not dependent on the skill of the professional responsible for its delivery (Gaume et al. 2008).

The costs associated with delivering Internet-based interventions are mostly incurred in developing and maintaining the intervention. The marginal cost per additional user is thought to be low, unlike formal in-person interventions (Linke et al. 2007; Murray 2009). If an Internet-based intervention is effective and used as intended, there are potential cost advantages of this approach over interventions delivered in-person. However, to date, there has been limited research into the cost-effectiveness of Internet-based interventions (Tate et al. 2009).

There are also disadvantages of delivering self-help interventions online. Internet access is not equitable. The digital divide separates those people that use the Internet from those that do not. The Internet may not be used for reasons of exclusion, such as lower socioeconomic status, lower income, or medical and physical disabilities; or for reasons of choice, such as retired or older people who may prefer different media outlets (Dutton et al. 2009). It has been suggested that Internet-based interventions could induce some of the problems they were designed to solve, such as isolation (Griffiths et al. 2006).

Internet-based interventions as a therapeutic approach have been criticised for their inability to respond to non-verbal cues or body language (Barak et al. 2008). Attrition from an Internet-based intervention, or treatment infidelity, is a concern as components necessary for behaviour change may not be accessed (Eysenbach 2005). The ease of accessing an Internet-based intervention may lead to higher numbers of less committed users, hence increasing the rate of drop-out (Christensen et al. 2006). In a trial of adults

recruited from a general population survey, one-third of participants in the experimental arm did not access the intervention, having previously expressed an interest in using an Internet-based intervention to check their alcohol intake and compare it with others (Cunningham et al. 2009). An Internet user is not necessarily a captive audience. They may not fully attend to the intervention if, for example, they are in a hurry, bored by the information or feel it is not relevant to them (Cunningham & Van Mierlo 2009).

### ***Internet-based interventions for reducing alcohol intake***

The Internet has the capacity to deliver the range of brief intervention approaches for hazardous and harmful drinkers, from simple to extended. Internet-based interventions can be made available from any location with Internet access and used as an easily accessible self-help resource. The feasibility and acceptability of these interventions in reducing alcohol intake has been demonstrated in a range of settings including primary care, university health centres, emergency departments, specialised treatment centres and among the general population (Bewick et al. 2008b; Copeland & Martin 2004; Kypri et al. 2005). Internet-based interventions could be offered as part of a stepped-care approach to treating alcohol problems (Kypri & Lee 2009), where electronic screening and personalised feedback is followed by a more extensive behaviour change website or access to a health care professional or therapist for those in need of further help. There is considerable demand for Internet-based alcohol interventions in the general population. In Canada, an online personalised feedback intervention received 500 hits per month (Cunningham et al. 2000). In the US, an extensive media campaign resulted in over 100,000 visitors a year to AlcoholScreening.org (Saitz et al. 2004). In the Netherlands, minderdrinken.nl (also known as Drink Less) receives around 2,750 unique visitors per month (Riper et al. 2009), and in the UK, the Down Your Drink (DYD) intervention website, an extensive behaviour change program, attracts more than 6,000 unique visitors a month



with no promotion other than links from various websites (Murray et al. 2009) (see Chapter 3 for detail on the DYD website).

There is now a substantive body of research to support the use of computer-based interventions for reducing alcohol consumption, particularly in student populations. The first effectiveness trial was conducted over a decade ago in a general population sample (Hester & Delaney 1997). In 2004, this remained the only trial in alcohol misusers according to a narrative review of web-based interventions for substance use disorders in all adult populations (Copeland & Martin 2004). Since 2004, this field has rapidly developed and to date there have been at least nine reviews of the literature, including the one presented in Chapter 2 (Bewick et al. 2008b; Carey et al. 2009; Elliott et al. 2008; Khadjesari et al. 2011; Kypri et al. 2005; Rooke et al. 2010; Vernon 2010; Walters et al. 2005; White et al. 2010). These reviews vary by the population of interest, the design of intervention and the synthesis of the data. Elliott et al. (2008) conducted a narrative review that identified seventeen trials of computer-based interventions (delivered on- and off-line) for college drinkers, finding them to be more effective than no treatment and as effective as alternative treatment approaches (Elliott et al. 2008). The first avowedly systematic review in this field, conducted by Bewick et al. (2008), concluded there was inconsistent evidence for the use of web-based electronic screening and brief intervention for reducing alcohol intake based on five trials in all adult populations (Bewick et al. 2008b). Carey et al. (2009) conducted a meta-analysis that found computer-delivered interventions to have a small effect at reducing the quantity and frequency of drinking in student populations when compared with assessment-only controls and found them as effective as other alcohol-related interventions (Carey et al. 2009). Another meta-analysis of computer-based interventions (both stand-alone and therapeutically-guided) for alcohol (28 trials) and tobacco use (13 trials) in all populations reported a significant reduction in substance use, demonstrated by a small effect size (Rooke et al. 2010). Most recently, a systematic

review of online alcohol interventions identified 17 trials and reported a range of pre-post effect sizes for different drinking outcomes (White et al. 2010).

In 2006, when first embarking on this thesis topic, there were no systematic reviews of computer-based interventions specifically for reducing alcohol intake. A scope of the literature identified around six studies, and hence this appeared a suitable starting point for this thesis (see Chapter 2). Despite the abundance of recently published reviews, this review provides a unique contribution to the field for a number of reasons outlined in Chapter 2.

### ***Evaluating Internet-based interventions online***

This thesis is also interested in the use of the Internet for evaluating Internet-based interventions. One limitation of the current research on brief interventions delivered both on- and offline, and of behavioural medicine in general, is that it lacks generalisability to the population of interest (Cunningham & Van Mierlo 2009; Glasgow 2008; Kypri 2007; Kypri & Cunningham 2008). Trials conducted over the Internet allow participants to access an Internet-based intervention as they would 'naturalistically', i.e. access the Internet from a remote location at their convenience, thus retaining the benefits of anonymity and flexibility (Murray et al. 2009). This improves the external (or ecological) validity of the trial, and allows for the conduct of pragmatic trials, "...to ensure generalisability pragmatic trials should, so far as possible, represent the patients to whom the treatment will be applied" p. 285 (Roland & Torgerson 1998).

There are several other advantages of conducting trials online. The Internet has the capacity to reach vast numbers of potential participants with relative ease, and thus meet or exceed sample size requirements (Eysenbach 2002; Murray et al. 2009). This is

particularly important in trials of brief interventions (including self-help resources) where sample sizes are generally low (Kypri 2007; Kypri & Cunningham 2008). Compared with conventional trials, online trials can reduce the cost for both the participant (e.g. time and cost of travel to research centre) and the research team (e.g. time and cost of the registration process, administering the intervention or control, data collection) (Eysenbach 2002; Murray et al. 2009). These advantages of online trial methodology have been realised by a large online trial of an Internet-based intervention for reducing alcohol consumption (the Down Your Drink trial - DYD RCT) (described in detail in Chapter 3). However, online trial methodology is still in its infancy. While online trials follow the same steps to minimise bias as conventional trials (Medical Research Council 1998), the online setting presents challenges of its own. This thesis explores some of the methodological challenges of evaluating Internet-based interventions online in the context of the DYD RCT; these are introduced in Chapter 3.

## Thesis aims and objectives

This thesis addresses two broad aims:

- To explore the use of the Internet for delivering alcohol interventions and to consider the implications for practice;
- To identify and address methodological challenges in undertaking online trials of Internet-based alcohol interventions, and to make recommendations for future conduct.

This thesis was designed to address these aims by reviewing the literature in the field and by exploring both the participant experience and the methodological issues encountered in a large externally-funded online trial of an Internet-based alcohol intervention (DYD RCT). The aims were investigated through a series of linked studies using different research methodologies.

The objectives were as follows:

- To systematically review the current literature on the effectiveness of computer-based interventions aimed at reducing alcohol intake;
- To determine the methodological quality of the data identified in the review;
- To determine the methodological challenges faced in the DYD online trial, to report on the characteristics of participants in this trial and outline the findings;
- To develop an online measure of alcohol consumption for use in the DYD trial;
- To assess the test-retest reliability of this online measure and its comparability with the in-person approach to eliciting past-week consumption;
- To determine the impact and costs of incentives on improving follow-up in the DYD trial;
- To determine the role of Internet-based interventions (DYD intervention) for people currently searching the Internet for help to reduce their drinking.

## Thesis structure

The first study in this thesis was a systematic review that determined the effectiveness of computer-based interventions for reducing alcohol intake and highlighted several methodological limitations of the literature in this field (Chapter 2). Some of these methodological challenges were then explored in the context of the Down Your Drink online trial (Chapter 3). Test-retest reliability and comparability studies were used to validate an online measure of alcohol consumption (Chapter 4). The use of incentives to reduce attrition from follow-up was investigated in two sequential randomised controlled trials (Chapter 5). Qualitative interviews were used to explore the participant's experience of searching for help online, using an Internet-based intervention for reducing their alcohol intake, and taking part in an online trial (Chapter 6). Each chapter provides the background to the specific study area, details of the methodology, presentation of the results and a related discussion. The final chapter of this thesis discusses the overall findings, their contribution to the knowledge base in this field of research, and future directions for Internet-based interventions. An outline of each chapter is provided below.

The systematic review described in Chapter 2 investigated the effectiveness of computer-based interventions for reducing alcohol intake. Chapter 2 describes the populations, interventions, comparators and outcomes used in the included studies. Mean differences were pooled in meta-analyses and a sensitivity analysis pooled studies using suitable measures of central tendency, providing a unique contribution to the literature. The risk of bias to trial results was also assessed. Online trials may render some conventional sources of bias obsolete; however, they may also introduce sources of bias not considered in conventional assessment tools. Some of the methodological challenges associated with online trials of Internet-based interventions are addressed in the following chapters of this

thesis. The review also pointed to gaps in the literature, providing direction for future research.

The Down Your Drink Internet-based intervention is described in Chapter 3, along with the online trial that evaluated its effectiveness. Although the development of this intervention and its evaluation did not provide an empirical contribution to this thesis, they provide the context for the methodological challenges investigated in Chapters 4 and 5. A description of the unique sample of people searching for help with their drinking online (DYD trial participants) also provides the context for the exploration of the participants' experience of seeking help online, using an Internet-based intervention, and taking part in an online trial (presented in Chapter 6).

One of the challenges in this field of research is selecting a suitable measure of alcohol intake, with numerous outcomes reported in previous research (see Chapter 2). An additional complexity is that conventional measures cannot be assumed to retain their psychometric properties when transferred online. The DYD online trial needed an online outcome measure to replicate the in-person approach to obtaining past-week alcohol intake – its primary outcome. The tool also needed to be easy to use and minimise reactivity of assessment. Chapter 4 reports on the development of an online measure of alcohol consumption (the TOT-AL), its test-retest reliability and comparability with the in-person approach of eliciting past-week drinking. The TOT-AL was the first freely available online measure of past-week alcohol intake that calculates units of alcohol. It also has the capacity to generate a number of different drinking outcomes using past-week data.

Chapter 5 considers the use of incentives to reduce attrition in the DYD RCT. Attrition from follow-up is a major methodological challenge in online trials and is a concern in studies of self-help interventions. Incentives are effective at boosting response to cross-

sectional postal and electronic surveys, but there has been limited research into their effect on follow-up in trials, particularly in online trials. The use of incentives was considered in the DYD trial as a means of improving follow-up without compromising anonymity or encouraging multiple registrations to the trial. The impact of different types and levels of incentives on improving follow-up in the DYD RCT was investigated through two sequential randomised controlled trials. The cost implications of offering incentives were also considered. Online trials have the capacity to recruit large numbers of participants and therefore incentives may have a substantial impact on research budgets.

The DYD online trial recruited a unique sample of hazardous and harmful drinkers searching online for help or information on their drinking. Qualitative interviews with these participants, described in Chapter 6, provided an illuminating insight into the experience of people searching for help online, using an Internet-based intervention (DYD intervention) and taking part in an online trial (DYD RCT). A further challenge in the evaluation of Internet-based interventions, as experienced in the DYD trial, is that the interventions are often not used as intended. Exploring the user's perspective provided an insight into what these people found helpful and unhelpful; this is important in shaping future services according to user need.

Chapter 7 discusses the main findings from the research in this thesis. It identifies further research needed to generate a robust evidence base for Internet-based interventions for reducing alcohol intake, and considers some of the broader issues of interest to this field, such as the future development of Internet-based interventions.

## Chapter 2: Computer-based interventions for reducing alcohol consumption – a systematic review

### ***Chapter overview***

Internet-based interventions have the potential to increase the availability of resources for hazardous drinkers and provide an anonymous setting for people to consider their drinking behaviour, thus addressing some of the barriers to delivering brief interventions in-person. Before Internet-based interventions are advocated by practitioners and policy makers, it is necessary to review their effectiveness. On conception of this thesis there were no systematic reviews of computer-based interventions for alcohol misuse, thus making a systematic review a suitable starting point for this thesis. The aim of the systematic review in this chapter was to determine the effects of computer-based interventions aimed at reducing alcohol consumption in adults. A number of systematic reviews have addressed a similar aim since this review was completed, demonstrating the emergence of this field. This review provides a valuable contribution to the knowledge base by investigating the impact of computer-based interventions on two different patterns of high-risk drinking (i.e. grams of alcohol per week and frequency of binges per week). The review highlights the importance of using suitable measures of central tendency with skewed distributions and identifies gaps in the literature related to study samples and comparator conditions. The methodological challenges related to the study of alcohol and Internet-based interventions are also explored and lead onto the research conducted in the following chapters of the thesis.



## ***Background***

In Chapter 1, the background to this thesis demonstrated the potential of Internet-based interventions to broaden the availability of services for hazardous and harmful drinkers by overcoming some of the barriers to accessing help in-person. In exploring this potential, this thesis began its empirical exploration of the use of the Internet for delivering alcohol interventions with a systematic review of the effects of computer-based interventions at reducing alcohol intake. At the time the review protocol was developed, this was a suitable starting point for this thesis given the emergence of evidence for these interventions and the absence of a systematic review (Kypri et al. 2005). Systematic reviews and meta-analyses of randomised controlled trials provide the highest level of evidence when investigating the effects of an intervention (Harbour & Miller 2001). They inform health care professionals and policy makers of the existing evidence for an intervention, thus contributing to evidence-based practice. Systematic reviews also provide directions for future research, illuminating both gaps in the literature and the methodological rigour of research conducted in the field.

Since 2006, when first embarking on this thesis, there have been at least six systematic reviews published in this field, including the one presented in this chapter (Bewick et al. 2008b; Carey et al. 2009; Elliott et al. 2008; Khadjesari et al. 2011; Rooke et al. 2010; White et al. 2010). These reviews have been conducted in the US, Australia and the UK, indicating widespread recognition of the potential benefits of these interventions. These reviews vary by population of interest, type of intervention, and method of data synthesis. Two were restricted to student samples (Carey et al. 2009; Elliott et al. 2008), two included web-based interventions alone (as opposed to computer-based) (Bewick et al. 2008b; White et al. 2010), and one included smoking cessation and alcohol misuse interventions both as stand-alone and therapeutically-guided interventions (Rooke et al. 2010). This review builds on those previously conducted by including stand-alone computer-based

interventions, available on- and offline, in all adult populations. Whilst hazardous drinking (particularly binge drinking) is highly prevalent among university students (Bewick et al. 2008a; Gill 2002; Wechsler et al. 1994), they represent a small proportion of adults in the general population known to be drinking at these levels. It is unknown whether the results from reviews in student populations generalise to the wider adult population drinking at hazardous and harmful levels, particularly as binge drinking while a student is known to be a transient phase (Bewick et al. 2008a; Schulenberg & Maggs 2002). Computer-based interventions encompass those available both on- and offline. The latter have the capacity to be made available online and therefore it is important to consider their effectiveness, particularly when online interventions are often evaluated on computers in a fixed location. Stand-alone interventions carry the benefits of reach, availability, anonymity and potential cost-effectiveness. This review was the first to include meta-analyses of mean differences in grams of alcohol and frequency of binges, giving the findings immediate clinical relevance. It was also novel in synthesising the findings of those studies that presented suitable measures of central tendency given the distribution of the data.

One methodological limitation of the studies in this field, highlighted by the Bewick review, is the lack of suitable statistics to account for the skewed distribution of the data (Bewick et al. 2008b). The distribution of alcohol consumption data in the general adult population is thought to be positively skewed, where most people are abstinent or drinking a relatively small amount of alcohol, while fewer people are consuming very large quantities (Horton et al. 2007; Kypri 2007; Orford 2001). In a skewed distribution, where sample sizes are small or moderate and the data contains extreme outliers, study data should be characterised by non-parametric methods or by transformation (Altman 1991). However, as Bewick indicated, many studies in this field do not follow this guidance. The extent to which different measures of central tendency (e.g. arithmetic mean vs. median) impact on the results are unknown, but any differences may have clinical significance and compromise

the robustness of the outcomes. This review explores this methodological issue in a sensitivity analysis and considers other methodological challenges evident in this field, some of which are explored further in this thesis.

### ***Aims, objectives and hypotheses***

The aim of this systematic review was to determine the effects of computer-based interventions aimed at reducing alcohol consumption in adults. Specific objectives were:

- To explore the clinical heterogeneity of the included studies by detailing the types of participants, interventions, comparator groups, and drinking outcomes;
- To assess the risk of bias associated with allocation concealment;
- To pool mean differences in meta-analyses where appropriate;
- To contribute to the evidence-base for computer-based interventions and make policy recommendations.

Hypothesis 1: Computer-based interventions are more effective than minimally active comparator groups at reducing alcohol consumption. Minimally active comparators do not constitute behaviour change interventions for reducing alcohol intake. They were termed 'minimally active' as opposed to 'control' conditions due to the impact of assessment on drinking behaviour (Carey et al. 2006; Kypri et al. 2007; McCambridge 2009; McCambridge & Day 2008) (discussed further in Chapters 3 and 4). Examples of eligible minimally active comparators included assessment-only, waiting-list control, usual care, generic non-personalised information or educational materials.

Hypothesis 2: Computer-based interventions are as effective as active comparator groups at reducing alcohol consumption. Active comparators were therapeutic, behaviour change interventions used to reduce alcohol consumption. Examples of eligible active comparator

groups included brief interventions delivered in-person, paper-based self-help materials, or electronic screening and brief intervention.

## ***Methods***

This review was conducted and reported in accordance with Cochrane and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidance (Higgins & Green 2009; Liberati et al. 2009).

### **Search strategy for identification of studies**

The following databases were searched for studies addressing the review question: The Cochrane Library (2008, issue 4), MEDLINE, EMBASE, CINAHL, PsychINFO, ERIC, Web of Science and the International Bibliography of the Social Sciences (IBSS). Each database was searched from inception to December 2008 with no restrictions on language. The databases were selected by examining those used in previous reviews of the alcohol and Internet literature, and through consultation with an information specialist (AY – see Acknowledgements). The search for published literature was supplemented with a search for unpublished literature, which included conference proceedings (Conference Proceedings Citation Index, formerly ISI Proceedings) and theses (Index to Theses). Attempts to identify unpublished studies are important in minimising publication bias, where studies showing beneficial effects are more likely to be published (Lefebvre et al. 2009).

The search strategy consisted of two themes: alcohol-related terms and computer-related terms. A preliminary scoping review of the literature in 2006 identified a small number of trials and as such, an RCT filter was not used. However, this proved to be an emerging field, with the majority of the literature published since 2006. Therefore, a post-hoc

decision was made to restrict inclusion to RCTs as they provide the highest level of evidence. An information specialist was consulted for help constructing the search strategy in accordance with Cochrane guidance. Search terms were selected by considering the inclusion criteria, scanning the background literature, and by browsing the MEDLINE Thesaurus (MeSH) (see Appendix 1 for MEDLINE search strategy). The thesaurus terms were redefined for each database. The purpose of this exhaustive search strategy was to achieve high sensitivity and therefore identify all the relevant literature in the field. The bibliographic records of studies identified by the search were imported into Reference Manager (version 11) software.

Included studies were citation tracked through Web of Science. This is a search for all of the studies that referenced those included in this review. The reference lists of relevant reviews and included studies were hand-searched for potentially eligible publications.

### **Selection criteria**

The eligibility criteria for study characteristics are reported using a structured approach, represented by the acronym PICOS, which considers each of the following aspects of the study: population, intervention, comparator, outcome and study design (Liberati et al. 2009).

### *Types of studies*

Studies were included if they randomly allocated participants to two or more study arms to determine their relative effectiveness.

### *Types of participants*

Studies of adult participants (aged 18 years and above) with any level of baseline alcohol consumption were eligible for inclusion, with the exception of studies that focussed on dependent drinkers. Studies of interventions aimed exclusively at dependent drinkers (as defined by the study authors) were excluded from the review as this group of alcohol misusers require specialist treatment that is care-planned and care co-ordinated, and delivered by specialist alcohol treatment services (DH / National Treatment Agency for Substance Misuse 2006). Such treatment cannot be delivered by a stand-alone computer-based intervention.

Most of the studies identified by an initial literature scope were in student populations. This guided the decision to include participants with any level of alcohol consumption. There is a high prevalence of hazardous drinking among student populations. As such, a primary prevention approach is sometimes used in university settings, for example, where an intervention is delivered to a classroom of students regardless of their alcohol intake. However, including studies that did not screen for hazardous drinking introduces the possibility of a floor effect, where alcohol consumption cannot be reduced in those participants who do not drink. An investigation into the impact of baseline risk on intervention effectiveness was planned for secondary analyses (see Discussion).

Studies including help- or non-help seeking participants were identified by the study's method of recruitment. This is an important distinction when interpreting the findings of the review as help-seekers have been found to benefit more from self-help interventions than those identified opportunistically through screening (Apodaca & Miller 2003).

### *Types of intervention*

Computer-based interventions aimed at reducing alcohol consumption were eligible for inclusion. Computer-based interventions included those delivered both online and offline (e.g. available from a computer in a fixed location). Offline interventions have the capacity to be made available online and hence their effectiveness was of equal interest. The Internet medium is essentially an effective means of mass dissemination (Murray 2009). The term 'computer-based intervention' was used when interventions were delivered by a computer, but were not necessarily available over the Internet.

Inclusion was restricted to stand-alone (self-guided) computer-based interventions as these have the capacity to be made available over the Internet and therefore carry the benefits of reach, availability, anonymity and potential cost-effectiveness. Participants could access the intervention from any setting, but studies of interventions that required facilitation by another individual (e.g. General Practitioner (GP), nurse, other health professional, researcher, alcohol specialist) were excluded from the review. Interventions delivered by CD-ROM, podcast, mobile telephone, interactive television, or any other digital format in addition to the Internet were eligible.

Studies evaluating a computer-based intervention as part of a multimodal intervention were included if it was possible to determine the effects of the computer-based intervention alone.

The terms 'computer-based interventions' and 'Internet-based interventions' were ambiguous in the e-health literature when first embarking on this review. They were used to encompass a broad range of health-related Internet-based activities, such as online counselling and therapy, internet-operated therapeutic software, and other online activities including blogs and forums (Barak et al. 2009). When the protocol for this review was

developed, computer-based interventions were defined as behavioural interventions aimed at bringing about positive behaviour change, adapted for a computer-based format, with components taken from effective face-to-face interventions, and often featuring tailored feedback, interactivity, use of multimedia, and self-determined pace (Ritterband 2003). There has since been a helpful review of the terminology used in this field, where the computer-based interventions included in this review (and thesis) fall under the category of self-guided web-based therapeutic interventions (Barak et al. 2009).

The content of the computer-based interventions included in this review were anticipated to vary, ranging from screening and personalised feedback to extensive behaviour change programs, such as computerised cognitive behavioural therapy (cCBT). It was therefore important to consider this potential heterogeneity when interpreting the findings of the review.

Websites or computer programs providing generic information on risky drinking (i.e. not personalised to the user) were excluded as they do not constitute a behaviour change, or therapeutic intervention.

#### *Types of comparator*

Eligible studies compared computer-based interventions with either a minimally active (e.g. assessment-only, usual care, generic non-personalised information or educational materials) or an active comparator group (e.g. brief intervention). These could be delivered in any format, for example, paper-based brochures or websites. Comparators were considered minimally active as opposed to inactive as they may have some impact on behaviour. For example, the process of assessment has been found to lead to a reduction in drinking (Carey et al. 2006; Kypri et al. 2007; McCambridge 2009;



McCambridge & Day 2008) – a phenomenon known as assessment reactivity (discussed further in Chapters 3 and 4).

### *Types of outcome measures*

Studies that measured a change in alcohol consumption were included in the review, where a reduction in alcohol consumption was considered as positive behaviour change. There is no internationally agreed ‘gold standard’ measure of alcohol consumption (discussed further in Chapter 4). Studies that reported any measure of alcohol intake over any time period were therefore eligible for inclusion. A change in alcohol consumption was chosen, rather than a measure of alcohol-related harm, given the preventative nature of the interventions. It also reflects the proximal goal of individual- and population level interventions (NICE public health guidance 24 2010), where increased alcohol consumption is a proximal measure of harm. Harm is not always experienced by hazardous drinkers and is experienced in many different ways in harmful drinkers, therefore making it difficult to measure.

### **Study screening and data extraction**

The study references identified by the search strategy were screened in duplicate with a second reviewer (SH – see Acknowledgments), but independently from each other. Both reviewers worked and trained together in systematic review methodology at the Centre for Reviews and Dissemination (University of York) from 2003 to 2005. Full papers were ordered for all potentially relevant studies and screened in duplicate. Discrepancies were resolved through discussion with a third party (EM – see Acknowledgments) and referral to the protocol. Data were extracted from the included studies into pre-designed forms (Microsoft Excel), which were piloted on three studies for suitability. The data extraction was verified for accuracy (EM). Authors were contacted for missing data.

## **Bias assessment**

The risk of bias associated with allocation concealment was assessed in each of the included studies as it is shown to have the greatest impact on treatment effect compared with other potential sources of bias (Hewitt et al. 2005; Kjaergard et al. 2001; Schulz et al. 1995). Bias assessment, as advocated by the Cochrane handbook (Higgins & Altman 2009), considers the likelihood that a particular aspect of trial quality would have biased the findings, given the design of the trial. Studies were classified as having high, low or unclear risk of bias (duplicated by EM). Discrepancies were resolved through discussion with a third party (CG – see Acknowledgments).

## **Data synthesis**

There is no ‘gold-standard’ measure of alcohol consumption; therefore, two outcomes that represent two different patterns of high-risk drinking were chosen for inclusion in the meta-analyses. Total alcohol consumption reflects chronic drinking, and binge drinking episodes measure heavy episodic drinking (where a ‘binge’ was defined by the authors of the primary studies). Mean weekly alcohol intake was chosen as the primary outcome for this review *a priori*, as it has been demonstrated to be a reliable index of alcohol-related problems (Borsari et al. 2001). Total alcohol consumption is also important at a population level for comparisons across populations and time (Babor 2003). A measure of binge drinking was chosen due to the large number of studies in student drinkers. Frequency of binges was the most commonly reported measure of binge drinking among the included studies and was therefore selected for pooling the data in meta-analyses.

Two specific measures of alcohol consumption were selected to allow for pooling of mean differences, i.e. total consumption (grams per week) and binge frequency (days / episodes per week). Mean differences are easily interpreted and provide a clinically meaningful

result. Previous meta-analyses in this field have presented standardised mean differences (SMD) (also known as effect sizes) which are ambiguously interpreted as small, moderate or large effect sizes (Carey et al. 2009). SMDs are used when an outcome is measured in many different ways, by standardising the results of studies to a common scale (i.e. dividing mean differences between groups by pooled SD) (Deeks et al. 2009).

Mean weekly alcohol intake (measured in grams) or number of binges per week, corresponding standard deviations, and numbers of participants in the intervention and comparator groups at follow-up were entered into Review Manager software v.5. Where outcomes were not presented per week, data were adjusted to represent this time frame (see Appendix 2 and 3). Where studies did not detail the number of grams included in a standard drink, information on country-specific standard units was obtained from an established source (Miller et al. 1991) (see Appendix 2 for conversion factors).

When more than one set of follow-up data were reported, data were extracted from the furthest point of follow-up unless a primary time-point was specified. The furthest point of follow-up demonstrates any long-term effect of the intervention and is also important at a population level.

In studies where data from the intervention and comparator groups are split, such as where results are presented separately for males and females in each study arm, these data were combined according to Cochrane guidance (Higgins & Deeks 2009). In studies where there were more than two experimental groups, decisions regarding the combination of data were discussed. For example, Kypri et. al. 2008 randomised participants to 1) assessment-only; 2) single-dose intervention; or 3) multiple-dose intervention. For this study, arms 2 and 3 were combined as the review was interested in

any dose of computer-based intervention (see Appendix 2 and 3 for all conversions made to the data).

A preliminary look at the data found that most studies had reported the arithmetic mean, whilst a few well-designed studies had reported the median and transformed data. This prompted consideration of the distribution of the data and whether the studies had presented suitable measures of central tendency. The distribution of alcohol consumption data is often skewed (Horton et al. 2007; Kypri 2007). When sample sizes are large, measures of central tendency (such as the arithmetic mean and median) approximate each other (known as the central limit theorem, see Discussion). The Cochrane Handbook states that “analyses based on means are appropriate for data that are at least approximately normally distributed, and for data from very large trials” (Deeks et al. 2009). However, in a skewed distribution where the sample sizes are small or moderate, the arithmetic mean is not a robust measure of central tendency: “when the data are skewed we can either use a non-parametric method, or try a transformation of the raw data” p.199 (Altman 1991). The data included in the meta-analyses were therefore assessed for skewness to determine whether suitable measures of central tendency had been used. The test for normality, advocated by Altman and Bland, was applied by dividing the mean by the standard deviation; where the ratio was less than two this indicated a skewed distribution (Altman & Bland 1996) (see Appendix 5).

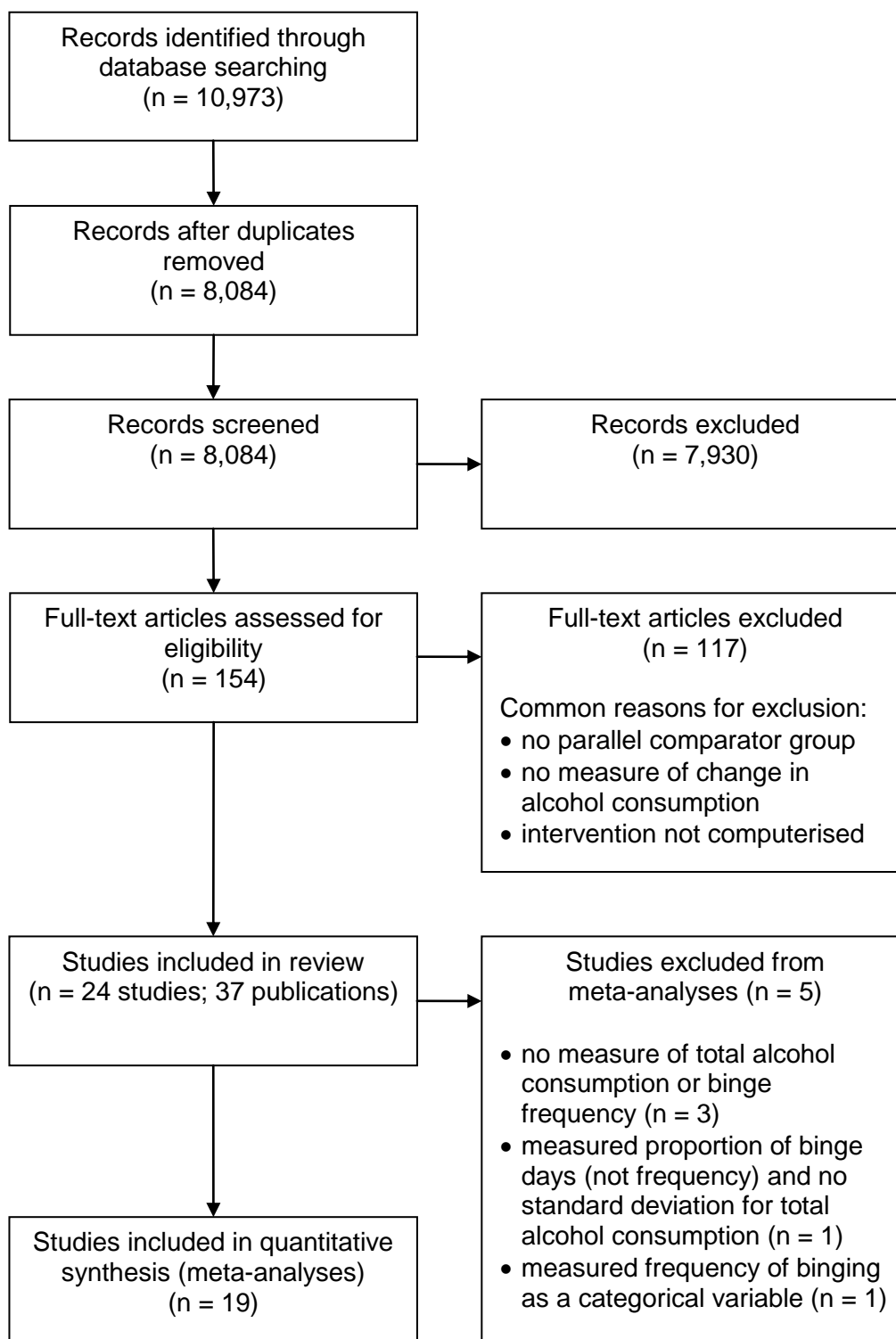
To allow for pooling of all data in meta-analyses, medians were used as the best estimate of the sample mean and an estimated standard deviation was generated from the range, using a method that makes no assumption on the distribution of the underlying data (Hozo et al. 2005). Log-transformed data were back-transformed before inclusion in meta-analyses.

Studies were pooled using the inverse variance method with a random effects model; all analyses were two-tailed. Studies comparing a computer-based intervention with a minimally active comparator group were pooled separately to those with an active comparator group. Heterogeneity was examined through use of forest plots, chi-squared test and I-squared test. A sub-group analysis by population (student vs. non-student), and timing of outcomes (short, medium and long-term) was planned *a priori*. A sensitivity analysis was conducted of those studies that used suitable measures of central tendency, given the distribution of the data. Analyses were checked for accuracy by a statistician (CH – see Acknowledgements).

## **Results**

A total of 8,084 citations were identified by the searches after removing duplicates. Of these, 154 were considered potentially relevant and screened at the full paper stage. Twenty-four studies (37 publications) met the inclusion criteria and were included in this review (see Figure 1. Flow-chart of study selection). All of the included studies were published in English and the majority were journal articles, with the exception of two US theses (Hedman 2007; Hunt 2004).

**Figure 1. Flow-chart of study selection**



Of the 117 papers that were excluded at the full paper stage, 75 were not randomised trials, 13 did not include computer-based interventions, 10 did not evaluate the intervention as stand-alone, eight did not measure a change in alcohol consumption, and five included participants all under the age of 18. One study compared a brief and extended version of the same computer-based intervention (Saitz et al. 2007), one compared the same intervention in Internet and paper-based format (Moore et al. 2005), one compared different ways of presenting personalised feedback (i.e. text only vs. multi-media) (Lieberman 2006), one investigated the intervention as an adjunct to treatment (Squires 2005), one was concerned with e-therapy (Postel et al. 2005) (see Table 1 for description), and one compared a computer-based intervention with a computer-based intervention plus self-help booklet (Cunningham et al. 2005) (see Table 1. Characteristics of excluded studies).

**Table 1. Characteristics of excluded studies**

<b>Study ID</b>	<b>Reason for exclusion</b>
(Bischof et al. 2008)	Intervention not evaluated as stand-alone. Computer-based intervention evaluated as part of a stepped-care approach.
(Cunningham et al. 2005)	Study compared computer-based intervention with computer-based intervention plus self-help book. It therefore assessed the impact of providing the self-help book.
(Dimeff 1998)	Intervention not evaluated as stand-alone. Feedback from computer-based intervention was reviewed with primary care provider. (Dimeff & McNeely 2000) – short report of Dimeff 1998.
(LaBrie et al. 2008)	Intervention not evaluated as stand-alone. Use of computer-based intervention was supplemented by a facilitated session, which included explanation of social norms theory and detailed explanation of feedback.
(Lieberman 2006)	Study compared different ways of presenting the same personalised feedback. One group received feedback in HTML format, whereas the other group received feedback in a multimedia Flash presentation.
(Miller 2001)	Intervention not evaluated as stand-alone. Computer-based intervention was accessed as part of a facilitated session, which included group discussion.
(Moore et al. 2005)	Study evaluated the impact of delivery mode (web-based vs. paper-based).
(Postel et al. 2005)	Study concerned with e-therapy. This approach used Internet communications to provide an ongoing personal relationship between therapist and client.
(Saitz et al. 2007)	Study compared a brief version of a computer-based intervention with a more extensive version. Both versions contained personalised feedback, drinking guidelines, symptoms of dependence and other useful information.
(Sharmer 2001)	Intervention not evaluated as stand-alone. Computer-based intervention was used in the context of a classroom activity. See also (Sharmer 2000) for PhD thesis.
(Squires 2005)	Computer-based intervention offered as adjunct to treatment as usual from a licensed treatment provider.
(Vinson 2000)	Intervention not evaluated as stand-alone. Participants used computer-based intervention to create behavioural contracts that were reviewed and signed by their physicians.



## Study description

### *Year of publication and country of origin*

The earliest study was published in 1997 (Hester & Delaney 1997), with four studies conducted in 2004 (Donohue et al. 2004; Hunt 2004; Kypri et al. 2004b; Neighbors et al. 2004), three conducted in 2005 (Chiauzzi et al. 2005; Hester et al. 2005; Kypri & McAnally 2005), three conducted in 2006 (Neighbors et al. 2006; Neumann et al. 2006; Paschall et al. 2006), seven conducted in 2007 (Barnett et al. 2007; Hedman 2007; Lewis et al. 2007; Lewis & Neighbors 2007; Matano et al. 2007; Walters et al. 2007; Weitzel et al. 2007), and six conducted in 2008 (Bewick et al. 2008c; Dumas & Hannah 2008; Dumas & Haustveit 2008; Kypri et al. 2008; Lau-Barraco & Dunn 2008; Riper et al. 2008b). The majority of studies were conducted in the United States (n=18) (Barnett et al. 2007; Chiauzzi et al. 2005; Donohue et al. 2004; Dumas & Hannah 2008; Dumas & Haustveit 2008; Hedman 2007; Hester et al. 2005; Hester & Delaney 1997; Hunt 2004; Lau-Barraco & Dunn 2008; Lewis et al. 2007; Lewis & Neighbors 2007; Matano et al. 2007; Neighbors et al. 2004; Neighbors et al. 2006; Paschall et al. 2006; Walters et al. 2007; Weitzel et al. 2007), three were conducted in New Zealand (Kypri et al. 2004b; Kypri et al. 2008; Kypri & McAnally 2005), one in Germany (Neumann et al. 2006), one in the Netherlands (Riper et al. 2008b) and one in the United Kingdom (Bewick et al. 2008c) (see Table 2. Characteristics of included studies).

**Table 2. Characteristics of included studies**

Study	Recruitment	Population	Intervention	Comparator	Drinking Outcomes	Follow-up time points	Follow-up at furthest time pt. %
Barnett et al. 2007	Voluntary alternative to individual session with university health educator after mandated health education session.	US: Mandated students	Alcohol 101 (n=113): Interactive computer-delivered intervention that features a virtual party where participants can observe the effects of gender, weight, drink type, and speed of consumption on BAC. Information on alcohol refusal skills, consequences of unsafe sex, multiple choice games and stories of actual campus tragedies involving alcohol. Personalised normative feedback was provided.	AC: Brief motivational interview (n=112)	1. No. of drinking days 2. No. of heavy drinking days 3. Average no. of drinks / drinking day 4. Average estimated BAC	3, 12 months	Intv:94 Cont:95
			Single session ± booster session.				
			Guiding principles not stated.				
			Intervention on CD-ROM; location determined by researcher.				
Bewick et al. 2008	Respondents of student experience survey.	UK: University students	Personalised feedback (n=234): Feedback on level of alcohol consumption and associated health risk, social norms information, and generic information such as calculating units, sensible drinking guidelines, support services.	MAC: Assessment only (n=272)	1. Units / occasion 2. Units / week	12 weeks	Intv:59 Cont:72
			Single session with continued access to the website for the study duration.				
			Based on social norms approach.				
			Intervention online; location determined by participant.				
Chiauzzi et al. 2005	Newspaper ads, flyers, and in-person at campus	US: University students	MyStudentBody.com: Alcohol (n=131) Interactive website that included 'Rate Myself', based on BASICS model and consisted of 4 sets of questions regarding	MAC: Alcohol and You: text-based, education-	1. Binge drinking days / week 2. Max. no. drinks / drinking day	1, 3 months	Intv:80 Cont:82

	locations and events.		<p>i) alcohol beliefs, ii) lifestyle issues, iii) risk taking while drinking, and iv) consequences resulting from drinking. Responses used to tailor feedback. The site also included articles, interactive tools, peer stories, ask the expert, and campus health news.</p> <p>Four weekly 20-minute sessions. Each session requiring completion before advancing to the next.</p> <p>Based on BASICS model.</p> <p>Intervention online; location determined by participant.</p>	only website containing articles on high-risk drinking (n=134)	<p>3. Drinks / week</p> <p>4. Drinking days / week</p> <p>5. Average consumption / drinking day</p> <p>6. Alcohol composite score</p> <p>7. Total consumption during special occasion drinking</p> <p>8. Peak consumption during special occasion drinking</p>		
Donohue et al. 2004	Not stated.	US: University students	<p>Alcohol 101 (n=40): Interactive computer-delivered intervention that features a virtual party where participants can observe the effects of gender, weight, drink type, and speed of consumption on BAC. Information on alcohol refusal skills, consequences of unsafe sex, multiple choice games and stories of actual campus tragedies involving alcohol. Personalised normative feedback was provided.</p> <p>Single session lasting approx. 45 mins.</p> <p>Guiding principles not stated.</p> <p>Intervention on CD-ROM; location determined by researcher.</p>	AC: Cognitive Behaviour Therapy (n=39)	<p>1. No. alcoholic beverages / past month</p> <p>2. No. days alcohol consumed / past month</p> <p>3. No. alcoholic beverages consumed / drinking occasion in past month</p>	1 month	Total:92
Doumas & Hannah 2008 <sup>a</sup>	Human resource departments of local companies were contacted for participation.	US: Workplace employees	<p>Check Your Drinking (n=60): Personalised normative feedback on drinking and associated risks. Also feedback on cost and calories associated with drinking, the rate at which the body processes alcohol, risk status for negative drinking-related consequences and problematic drinking based on AUDIT score.</p> <p>Single session.</p>	<p>1. MAC: control - assumed assessment only (n=73)</p> <p>2. 3<sup>rd</sup> arm excluded: Check Your Drinking plus</p>	<p>1. Weekend drinking</p> <p>2. Peak consumption (quantity)</p> <p>3. Frequency of drinking to intoxication</p>	30 days	Total:63

			Based on social norms approach and motivational enhancement models.	motivational interview.			
			Intervention online www.checkyourdrinking.net Location determined by researcher.				
Doumas & Haustveit 2008	University athletics department.	US: Collegiate athletes	Check Your Drinking (n=28): Personalised normative feedback on drinking and associated risks. Also feedback on cost and calories associated with drinking, the rate at which the body processes alcohol, risk status for negative drinking-related consequences and problematic drinking based on AUDIT score.	MAC: Educational website containing alcohol facts and consumption guidelines <a href="http://www.radford.edu/kcastleb/toc.html">http://www.radford.edu/kcastleb/toc.html</a> (n=24).	1. Weekly drinking quantity 2. Peak consumption (quantity) 3. Frequency of drinking to intoxication	6 weeks, 3 months	Intv:54 Cont:75
			Single session lasting 15 mins.				
			Based on social norms approach and motivational enhancement models.				
			Intervention online <a href="http://notes.camh.net/efeed.nsf/newform">http://notes.camh.net/efeed.nsf/newform</a> Location determined by researcher.				
Hedman 2007	Health, Sport, and Exercise Science department.	US: University students	Personalised feedback (n=68): Personalised feedback consisted of peak blood alcohol level, time to alcohol oxidation, dollars spent on alcohol, caloric intake, alcohol-related risks, info. on sensible drinking behaviours. Feedback was supplemented with health communication messages on risks and consequences associated with heavy alcohol consumption.	MAC: Alcohol facts received via email twice a week for 6 weeks (n=63)	1. 30-day frequency of alcohol use (>1 drink) 2. No. of typical drinks reported at one setting in past 30 days 3. 30-day frequency of binge drinking 4. 14-day frequency of binge drinking	6 weeks	Intv:60 Cont:57
			Viewed feedback via email, followed by health communication messages twice a week for 6 weeks.				
			Based on Health Belief Model, Cognitive Dissonance Theory, Elaboration Likelihood Model.				
			Intervention via email; location determined by participant.				

Hester & Delaney 1997	Local health centre, other health / mental health care providers, screening program for driving while intoxicated, and via media adverts.	US: Adult problem drinkers in the general population	Behavioural Self-Control Program for Windows (n=20): Teaches the following skills: goal-setting, self-monitoring, rate control and drink refusal, behavioural contracting, evaluating triggers and problem solving, functional analysis of drinking, and relapse prevention. Also provided normative feedback.	MAC: Wait-list control (n=20)	1. Total drinks per week 2. Estimated peak BAC per week 3. No. of drinking days per week	10 weeks	Intv:100 Cont:100
			Eight weekly sessions over 10 weeks.				
			Based on Miller and Munoz (1982) protocol for self-control training (Miller & Munoz 1982).				
			Intervention on disk; location determined by researcher (except for 2 ppts. who used their home computers).				
Hester et al. 2005	Media adverts.	US: Adult problem drinkers in the general population.	Drinker's Check-up (n=35): Consisted of assessment (including decisional balance exercise), feedback, and decision-making (including Rollnick's 'Readiness Ruler', negotiating goals of change and developing alternatives and a change plan) modules.	MAC: Wait-list control (n=26)	1. Average drinks per day 2. Drinks per drinking day 3. Average peak BAC	4 weeks	Not reported at 4 weeks
			Approx. 90 minutes to complete. Summary of worksheets and feedback from completed assessments were printed.				
			Based on FRAMES and MI approach.				
			Intervention online <a href="http://www.drinkerscheckup.com">www.drinkerscheckup.com</a> Location determined by researcher.				
Hunt 2004 <sup>b</sup>	Online participant pools from psychology departments across three sites.	US: University students	Expectancy challenge (n=52): Video of people undergoing an alcohol / placebo expectancy-disconfirming experience followed by description of alcohol expectancy concept and effect of alcohol expectancies on behaviour. The program had audiovisual elements, including	1. MAC: Power-point presentation on safe driving practices (n=54)	1. Mean drinks consumed per day 2. Quantity / frequency 3. Proportion of binge days	1 month	Not reported

			games and questions requiring interaction.	2. 3 <sup>rd</sup> arm excluded: Non-interactive power-point presentation of expectancy challenge.			
			Approx. 20 minutes.				
			Based on the expectancy concept (Goldman 1999).				
			Intervention computer-based; location determined by researcher.				
Kypri et al. 2004b	University health centre.	NZ: University students	Personalised feedback (n=51): Feedback consisted of a summary of recent consumption and comparison with recommended limits, estimate of BAC for heaviest drinking session (criterion feedback), normative feedback and correction of norm misperceptions. Participants also received the leaflet provided in the control condition.	MAC: Participants received a paper-based leaflet on alcohol facts and effects (n=53)	1. Frequency of drinking 2. Typical occasion quantity 3. Total volume 4. Frequency of heavy episodes	6 weeks, 6 months	Intv:92 Cont:89
			Single session 10-15 minutes.				
			Feedback component of brief intervention and motivational interviewing (Miller & Rollnick 2002).				
			Intervention online; location determined by researcher.				
Kypri & McAnally 2005 <sup>a</sup>	University health centre.	NZ: University students	Personalised feedback (n=72): Feedback consisted of health authority recommendations, social norms and self-comparison. Blood pressure and demographic details were also taken.	1. MAC: Assessment-only (comprising of blood pressure, demographic data and assessment) (n=74) 2. 3 <sup>rd</sup> arm excluded: Minimal contact	1. Percent compliance with recommendations (alcohol consumed per occasion) 2. Peak estimated BAC	6 weeks	Intv:85 Cont:88
			Single session.				
			Feedback component of brief intervention and motivational interviewing (Miller & Rollnick 2002).				
			Intervention online; location determined by researcher.				

				(blood pressure and demographic data).			
Kypri et al. 2008	University health centre.	NZ: University students	<p>Personalised feedback plus information pamphlet on health effects of alcohol consumption (single and multi-dose groups combined) (n=283): Feedback consisted of risk status, summary of recent consumption, comparison of consumption with recommended limits, estimate of blood alcohol concentration for heaviest drinking occasion in past 4 weeks, comparison of consumption with national and university norms and correction of misperceptions of norms.</p> <p>Single-dose: single session of assessment and feedback at baseline. Multi-dose: assessment and feedback at baseline, 1 and 6 months.</p> <p>Feedback component of brief intervention and motivational interviewing (Miller &amp; Rollnick 2002).</p> <p>Intervention online; location determined by researcher.</p>	MAC: Screening and information pamphlet on health effects of alcohol consumption (n=146)	<p>1. Frequency of drinking</p> <p>2. Typical occasion quantity</p> <p>3. Total volume</p> <p>4. Frequency of heavy episodes</p>	6, 12 months	Intv:83 Cont:86
Lau-Barraco & Dunn 2008	Psychology classes.	US: University students	<p>Alcohol 101 (n=39): Information on the effects of alcohol misuse and drinking behaviour among peers (see Barnett et al. 2007 and Donohue et al. 2004).</p> <p>Single session lasting 90-120 minutes.</p> <p>Guiding principles not stated.</p> <p>Intervention on CD-ROM; location determined by researcher.</p>	<p>1. AC: Expectancy challenge (n=114)</p> <p>2. MAC: Assessment only (n=64)</p>	<p>1. Average drinks / week</p> <p>2. Heavy episodic drinking frequency</p>	Post-test, 1 month	Intv:89 Cont (MAC): 93 Cont (AC):91
Lewis et al. 2007	Orientation course.	US: University students	Normative feedback (gender-specific and gender-neutral groups combined) (n=157): Feedback on personal drinking behaviour, personal perceptions of typical	MAC: Assessment only (n=88)	<p>1. Drinks / week</p> <p>2. Drinking frequency</p>	5 months	Intv (combined):83 Cont:89

			<p>student drinking behaviour, information on actual norms for typical student drinking behaviour.</p> <p>Feedback viewed on screen then provided as printout.</p> <p>Based on social norms approach.</p> <p>Intervention online; location determined by researcher.</p>				
Lewis & Neighbors 2007	Psychology classes.	US: University students	<p>Normative feedback (gender-specific and gender-neutral groups combined) (n=125): Feedback on personal drinking behaviour, perceptions of typical student drinking behaviour, information on actual norms for typical student drinking behaviour.</p> <p>Feedback viewed on screen for 1 to 2 minutes then provided as printout.</p> <p>Based on social norms approach.</p> <p>Intervention computer-based; location determined by researcher.</p>	MAC: Assessment only (n=57)	<p>1. Overall consumption (Alcohol Consumption Inventory)</p> <p>2. Typical weekly drinking</p> <p>3. Typical no. drinks consumed / drinking occasion</p>	1 month	Total:89
Matano et al. 2007 <sup>a</sup>	Mailed recruitment flyer.	US: Workplace employees	<p>Coping Matters (n=not reported, total sample=145): Provided individualised feedback on risk of alcohol-related problems, recommendations, mini-workshops, drinking journal, and links to online resources. Feedback was also given on stress level and use of coping strategies.</p> <p>Participants had access to the website for 90 days.</p> <p>Based on concepts derived from social learning perspective.</p> <p>Intervention online; location determined by participant.</p>	MAC: Computer-based individualised feedback on stress level and coping strategies but not alcohol consumption (n=not reported, total sample=145).	<p>1. Frequency of drinking</p> <p>2. Usual no. of beers consumed when drinking</p> <p>3. Usual no. of glasses of wine consumed when drinking</p> <p>4. Usual no. of shots of hard liquor when drinking</p> <p>5. Most no. of beers consumed when drinking</p> <p>6. Most no. of glasses of wine consumed when drinking</p> <p>7. Most no. of shots of hard liquor when drinking</p> <p>8. Frequency of beer binges</p>	3 months	Total:84



					9. Frequency of wine binges 10. Frequency of hard liquor binges		
Neighbors et al. 2004	Psychology classes.	US: University students	Normative feedback (n=126): Consisted of perceived drinking norms compared with actual drinking norms, and summary of reported consumption compared with average college drinking behaviour. Also feedback on percentile ranking compared with other college student drinking.	MAC: assessment only (n=126).	1. Overall consumption (Alcohol Consumption Index) 2. Typical weekly drinking 3. Peak quantity	3, 6 months	Total:82
			Viewed feedback on screen for approx. 1 minute while printing.				
			Based on social norms approach.				
			Intervention computer-based; location determined by researcher.				
Neighbors et al. 2006	Psychology classes.	US: University students	Normative feedback (n=108): Consisted of perceived drinking norms for quantity and frequency of alcohol intake compared with actual quantity and frequency norms, and summary of reported consumption compared with actual norms. Also feedback on percentile ranking compared with other college student drinking.	MAC: assessment only (n=106)	1. No. of drinks / week	2 months	Intv:91 Cont:82
			Feedback viewed on screen for 1 to 2 minutes then provided as printout.				
			Based on social norms approach.				
			Intervention computer-based; location determined by researcher.				
Neumann et al. 2006	Emergency department after initial care.	Germany: Emergency department attendees	Brief intervention (n=561): Feedback on current drinking status based on AUDIT and Readiness to Change responses. The intervention contained feedback on comparison of consumption with safe drinking levels, personal responsibility for change, advice on need to change drinking and on developing goals for	MAC: usual care (n=575)	1. Proportion of at-risk drinking 2. Alcohol intake (grams / day)	6, 12 months	Intv:55 Cont:61

			change. Alternative strategies for changing consumption were provided (treatment-assisted or self-change). Alcohol-related feedback was imbedded with information about other lifestyle risks. Participants also had access to usual care.				
			Results were presented on screen, printed and provided to participant.				
			Based on FRAMES model.				
			Intervention computer-based; location determined by researcher.				
Paschall et al. 2006 <sup>c</sup>	Campus orientation sessions and by letter and email.	US: University students	College Alc (n=310): Alcohol misuse and harm prevention course, consisted of 5 units: College Alcohol Use, Harm Prevention, How it Works, Risky Business and Practical Solutions. Encourages development of a harm prevention plan. The program includes interactive animation and assignments, challenges normative misconceptions and alcohol expectancies.	MAC: assessment only (n=312).	1. Frequency of alcohol use in past month. 2. Frequency of heavy drinking in past month. 3. Frequency of feeling drunk in past month.	30 days	Intv:56 Cont:63
			Approx. 3 hours (participants given 6 weeks for completion).				
			Theories of problem- and health-related behaviour (Ajzen 1988; Jessor & Jessor 1977).				
			Intervention online; location determined by participant.				
Riper et al. 2008b	Newspaper adverts and via health-related websites.	NL: Adult problem drinkers in the general population	Drinking Less (n=130): Consisted of 4 stages: i) preparing for action, ii) goal-setting, iii) behavioural change, and iv) maintenance of gains and relapse prevention. Access to peer-to-peer discussion forum.	MAC: Web-based psycho-educational brochure describing impact of alcohol use	1. No. of problem drinkers 2. Mean weekly alcohol consumption.	6 months	Intv:54 Cont:62
			Recommended treatment period of 6 weeks. Measured actual use of the				

			intervention. Based on cognitive behavioural and self-control principles. Intervention online <a href="http://www.minderdrinken.nl">http://www.minderdrinken.nl</a> Location determined by participant.	on physical and social functioning (n=131).			
Walters et al. 2007	Not stated	US: University students	e-CHUG (n=50): Personalised feedback consisted of 1) quantity/frequency drinking summary (including caloric 'cheeseburger' equivalent); 2) comparison to US adult and college norms; 3) estimated level of risk; 4) money spent on alcohol per year; 5) no. cigarettes smoked per month; 6) advice and local services. Feedback was derived from responses to AUDIT, questions on genetic risk of alcoholism, weight and expenditure on alcohol. Single session where feedback was viewed on screen. Feedback based on Motivational Interviewing and social psychology approaches. Followed FRAMES model. Intervention online <a href="http://www.e-chug.com">www.e-chug.com</a> Location determined by participant.	MAC: assessment only (n=56).	1. Typical drinks / week 2. Peak BAC	8, 16 weeks	Total:77
Weitzel et al. 2007	Flyers, emails and adverts.	US: University students	Hand-held computer with messaging (n=20): Tailored text messages sent to hand-held computer daily on avoiding alcohol-related consequences. Messages addressed three situations: 1) drinking with negative consequence, 2) drinking without consequence, 3) not drinking. Messages were tailored to behaviour, self-efficacy, and outcome expectancies regarding alcohol-related consequences. Messages were sent daily to those ppts. providing consumption data. Number of	1. MAC: Hand-held computer without messaging (n=20). 2. 3 <sup>rd</sup> arm excluded from publication.	1. Total drinks consumed in study period 2. Drinking days 3. Drinks / drinking day	2 weeks	Intv:100 Cont:100

			messages sent to and read by ppts. was recorded.				
			Guiding principles not stated.				
			Intervention computer-based; location determined by participant.				

AC: active comparator group; MAC: minimally active comparator group; Intv: intervention; Cont: control/comparator; UK: United Kingdom; US: United States of America; NZ: New Zealand; NL: Netherlands; FRAMES: Feedback, Responsibility, Advice, Menu, Empathy and Self-efficacy (Miller & Sanchez 1994); MI: motivational interview (Miller & Rollnick 2002); BASICS: Brief Alcohol Screening and Intervention for College Students (Dimeff et al. 1999); BAC: blood alcohol concentration; AUDIT: Alcohol Use Disorders Identification Test (Babor et al. 2001); <sup>a</sup>excluded from meta-analyses as no measure of total alcohol consumption or binge frequency; <sup>b</sup>excluded from meta-analyses for providing proportion of binge days and no standard deviation total alcohol consumption; <sup>c</sup>excluded from meta-analyses for providing frequency of heavy drinking as a categorical variable.

### *Participants*

Students were the most commonly studied population group (n=18) (Barnett et al. 2007; Bewick et al. 2008c; Chiauzzi et al. 2005; Donohue et al. 2004; Doumas & Haustveit 2008; Hedman 2007; Hunt 2004; Kypri et al. 2004b; Kypri et al. 2008; Kypri & McAnally 2005; Lau-Barraco & Dunn 2008; Lewis et al. 2007; Lewis & Neighbors 2007; Neighbors et al. 2004; Neighbors et al. 2006; Paschall et al. 2006; Walters et al. 2007; Weitzel et al. 2007), with a further three studies of adult problem drinkers from the general population (Hester et al. 2005; Hester & Delaney 1997; Riper et al. 2008b), two of workplace employees (Doumas & Hannah 2008; Matano et al. 2007), and one of emergency department attendees (Neumann et al. 2006). All studies appeared to include non-help-seeking participants according to trial recruitment procedures (see Table 2. Characteristics of included studies); albeit possible that some participants may have answered trial advertisements in the hope they would receive help with reducing their drinking.

### *Screening*

The majority of studies used some form of screening tool to assess the eligibility of participants based on their level of alcohol intake (see Table 3. Characteristics of study participants). Thirteen studies appeared to screen for hazardous drinking, either in the form of binge drinking, total number of drinks per week, AUDIT cut-off score (generally reported as  $\geq 8$ ) or some combination of these (Chiauzzi et al. 2005; Hedman 2007; Hester et al. 2005; Hester & Delaney 1997; Kypri et al. 2004b; Kypri et al. 2008; Lau-Barraco & Dunn 2008; Lewis et al. 2007; Lewis & Neighbors 2007; Neighbors et al. 2004; Neighbors et al. 2006; Neumann et al. 2006; Riper et al. 2008b).

Three studies used a lower cut-off score, for example more than one drink in the past week (Donohue et al. 2004; Hunt 2004; Weitzel et al. 2007). There were eight studies that

did not screen participants for inclusion (Barnett et al. 2007; Bewick et al. 2008c; Dumas & Hannah 2008; Dumas & Haustveit 2008; Kypri & McAnally 2005; Matano et al. 2007; Paschall et al. 2006; Walters et al. 2007). One of these studies recruited mandated students, where intoxication or an alcohol-related violation had led to participation in the research (Barnett et al. 2007); three studies analysed low and moderate / high risk groups separately (Dumas & Hannah 2008; Dumas & Haustveit 2008; Matano et al. 2007), whereas another study excluded from analyses those participants with no binge drinking episodes (Walters et al. 2007).

**Table 3. Characteristics of study participants**

Study	Female (%)	Age (mean years)	White (%)	Screening test and cut-off score
Barnett et al. 2007	51	18.8	75.6	Not used (mandated students)
Bewick et al. 2008	69	21.3	-	Not used
Chiauzzi et al. 2005	54	Intervention: 20 Control: 19.8	73.2	Daily drinking questionnaire
				Binge drinkers: $\geq 5$ ♂/4♀ drinks, per drinking occasion in the past week
Donohue et al. 2004	56	20.6	62.6	Time-line follow-back
				$\geq 1$ alcoholic drink in past 30 days
Dumas & Hannah 2008	73	Range: 18-24	87	Binge drinking: $\geq 5$ ♂/4♀ drinks in row, in past 2 weeks
				All participants included but separated into low and high risk for analysis
Dumas & Haustveit 2008	42	18.1	54	Binge drinking: $\geq 5$ ♂/4♀ drinks in row, in past 2 weeks
				All participants included but separated into low and high risk for analysis
Hedman 2007	58	19.5	93.8	Binge drinking: $\geq 5$ ♂/4♀ drinks in row, at least once in 2 weeks preceding survey
Hester & Delaney 1997	40	36.3	70	MAST and AUDIT
				AUDIT score $\geq 8$ ; $\geq 120$ ♂/70♀ drinks per month; weekly drinking

				with ≥6 drinks per episode; drinking at least once per week
Hester et al. 2005	48	46.1♂	79	AUDIT
		45.2♀		AUDIT score ≥8
Hunt 2004	0	21.2	Presented separately for each site.	Time-line follow-back
				6 drinks per week and less than 6 drinks per day
Kypri et al. 2004b	50	Intervention: 19.9	-	AUDIT
		Control 20.4		AUDIT score ≥8; >6♂/4♀ drinks on at least one occasion in preceding 4 weeks
Kypri & McAnally 2005	49	20.2	75	Not used
Kypri et al. 2008	Intervention: 52	Intervention: 20.1	-	AUDIT
	Control: 52	Control 20.1		AUDIT score ≥8
Lau-Barraco & Dunn 2008	57	20	76	≥2 heavy episodic drinking occasions (in past 30 days), or ≥5 weekly standard drinks (but fewer than 40)
Lewis et al. 2007	52	19	99.6	≥1 heavy drinking episode in past month (≥5♂/4♀ drinks in one sitting)
Lewis & Neighbors 2007	55	20	97	≥1 heavy drinking episode in past month (≥5♂/4♀ drinks in one sitting)
Matano et al. 2007	78	40	83	AUDIT and CAGE
				Participants separated into low and moderate risk for analysis. High risk participants were excluded.
Neighbors et al. 2004	59	18.5	79.5	≥1 heavy drinking episode in past month (≥5♂/4♀ drinks)
Neighbors et al. 2006	56	19.7	98	≥1 heavy drinking episode in past month (≥5♂/4♀ drinks)
Neumann et al. 2006	Intervention: 20	Intervention: median 30	-	AUDIT
	Control: 22	Control: median 31		AUDIT score ≥ 5
Paschall et al. 2006	52	18.1	30.3	Not used
Riper et al. 2008b	Intervention: 49	Intervention: 45.9	-	Weekly recall and quantity- frequency variability index of alcohol intake

	Control: 49	Control: 46.2		> 21♂/14♀ units per week or ≥ 6♂/4♀ units at least one day per week for past 3 months (1 unit = 10g ethanol)
Walters et al. 2007	48	-	72.7	Not used
				Ppts. with at least one heavy drinking episode in past month (≥5 drinks ♂, ≥4 drinks ♀) were included in the analysis
Weitzel et al. 2007	55	19.2	75	Drinking more than once a week

AUDIT: Alcohol Use Disorders Identification Test (Babor et al. 2001); MAST: Michigan Alcohol Screening Test (Selzer 1971); CAGE: mnemonic for cut-down, annoyed, guilty, eye-opener (Mayfield et al. 1974).

### *Comparator groups*

The majority of studies (n=22) compared a computer-based intervention with a minimally active comparator group. Minimally active comparators consisted mainly of assessment-only (Bewick et al. 2008c; Dumas & Hannah 2008; Kypri & McAnally 2005; Lau-Barraco & Dunn 2008; Lewis et al. 2007; Lewis & Neighbors 2007; Neighbors et al. 2004; Neighbors et al. 2006; Neumann et al. 2006; Paschall et al. 2006; Walters et al. 2007). Five studies used an information-only website or leaflet (Chiauzzi et al. 2005; Dumas & Haustveit 2008; Kypri et al. 2004b; Kypri et al. 2008; Riper et al. 2008b), one study emailed alcohol-related facts to participants (Hedman 2007), two included wait-list controls (Hester et al. 2005; Hester & Delaney 1997), one provided a PowerPoint presentation on safe-driving practices (Hunt 2004), one required participants to report their consumption everyday for two weeks (Weitzel et al. 2007), and one consisted of individualised feedback on stress level and coping strategies (unrelated to alcohol) (Matano et al. 2007).

Three studies compared a computer-based intervention with an active comparator group. One of these studies was a three-arm trial that compared a computer-based intervention with both a minimally active and an active comparator group (Lau-Barraco & Dunn 2008). Active comparator groups consisted of an in-person motivational interview (Barnett et al.



2007), cognitive behaviour therapy (Donohue et al. 2004) and an expectancy challenge (Lau-Barraco & Dunn 2008). In two of the above studies (Barnett et al. 2007; Lau-Barraco & Dunn 2008), the authors hypothesised that the active comparator would be more effective than the computer-based intervention. The third study did not state a hypothesis (Donohue et al. 2004).

Four studies had more than one comparator arm, and in all cases the third-arm was considered ineligible for inclusion. One of these studies had a third arm that consisted of computer-based intervention plus motivational interview (Dumas & Hannah 2008). In this study a comparison of computer-based intervention with computer-based intervention plus motivational interview would measure the additional effectiveness of the interview. In another study (Hunt 2004), the third arm consisted of a non-interactive version of the computer-based intervention, presented in the form of a PowerPoint presentation. Kypri 2005 and 2008 had a minimal contact arm (consisting of blood pressure and demographic data) that was excluded as there were no assessment data (Kypri et al. 2008; Kypri & McAnally 2005).

#### *Intervention - delivery mode*

Most studies delivered the intervention via the Internet (n=14), one study sent tailored text-messages to hand-held computers (Weitzel et al. 2007), whilst the others were available from a computer in a fixed location. Most interventions were accessed from computers in a location determined by the researchers (n=16); the remainder were accessed online at a location and time convenient to the participant (Bewick et al. 2008c; Chiauuzzi et al. 2005; Hedman 2007; Matano et al. 2007; Paschall et al. 2006; Riper et al. 2008b; Walters et al. 2007; Weitzel et al. 2007).

### *Intervention - content*

Most computer-based interventions in these studies aimed to reduce alcohol intake (this was sometimes specified as at-risk or binge drinking) and alcohol-related harm. Some interventions were aimed at changing normative misperceptions or alcohol expectancies (see description of Hunt 2004 below) with the hypothesis that this would subsequently lead to a reduction in alcohol intake.

Fifteen studies consisted of personalised feedback on current levels of drinking and comparison with safe drinking limits. This was often accompanied with normative feedback (see Box 1), associated health risk, information on calculating units, and details of support services (Bewick et al. 2008c; Neighbors et al. 2004; Neighbors et al. 2006). Some interventions also provided feedback on the cost and calories associated with drinking, negative consequences associated with problem drinking and estimated peak Blood Alcohol Concentration (BAC) (Doumas & Hannah 2008; Doumas & Haustveit 2008; Hedman 2007; Kypri et al. 2004b; Kypri et al. 2008; Walters et al. 2007; Weitzel et al. 2007). Two studies compared gender-neutral with gender-specific normative feedback (Lewis et al. 2007; Lewis & Neighbors 2007) (which were combined for inclusion in meta-analyses). One study combined alcohol-related feedback with feedback on physical activity, fruit and vegetable consumption and smoking (Kypri & McAnally 2005). One study provided additional feedback on stress and coping strategies. It also looked at alcohol expectancies and provided a drinking journal (Matano et al. 2007). One study supplemented personalised feedback with information on personal responsibility for change, developing change goals and alternative strategies for achieving change. Alcohol-related feedback was imbedded with information about other lifestyle risks (Neumann et al. 2006).

Five studies investigated interventions designed to resemble the campus setting. These included a variety of interactive games and assignments, motivational feedback, and information on risk taking and refusal skills (Barnett et al. 2007; Chiauuzzi et al. 2005; Donohue et al. 2004; Lau-Barraco & Dunn 2008; Paschall et al. 2006). Another study presented a video of people undergoing an alcohol / placebo expectancy-disconfirming experience. This aimed to increase awareness of how participants expected alcohol to affect them, and how these expectancies can lead to detrimental effects. It was followed by a description of the alcohol expectancy concept and the impact of alcohol expectancies on behaviour. The intervention also included games and questions requiring interaction (Hunt 2004).

Three studies based in adult problem drinkers from the general population provided a more extensive intervention, featuring common elements from behaviour change interventions. They included components such as readiness to change, decisional-balance, goal-setting, self-monitoring, strategies for behaviour change, behavioural contracting with rewards and penalties, maintenance of change and relapse prevention (Hester et al. 2005; Hester & Delaney 1997; Riper et al. 2008b). One of these studies also provided access to a peer-to-peer discussion forum (Riper et al. 2008b) (see Table 2 for more information).

The studies addressed the spectrum of preventive approaches. The type of preventive approach was determined by the study's screening criteria rather than the content of the intervention, where the same intervention was used as primary prevention in one study that screened for at least one alcoholic drink in past 30 days (Donohue et al. 2004), secondary prevention in a second study where students were assessed for hazardous drinking (at least two heavy episodic drinking occasions in past 30 days) (Lau-Barraco &

Dunn 2008), and tertiary prevention in a third study that included mandated students (Barnett et al. 2007).

#### *Intervention - theoretical basis*

The studies cited different theoretical foundations of their interventions. Personalised feedback was reported to have originated from Motivational Interviewing (Miller & Rollnick 2002); FRAMES (Feedback, Responsibility, Advice, Menu, Empathy and Self-efficacy - illustrates effective components from brief intervention) (Miller & Sanchez 1994); BASICS (Brief Alcohol Screening and Intervention for College Students) (Dimeff et al. 1999); and the social norms approach (Borsari & Carey 2001; Perkins 2002; Perkins & Berkowitz 1986). In those studies that used a more extensive range of behaviour change techniques, self-control training and cognitive behaviour therapy were referenced (Hester 1995; Miller & Munoz 1982). Three studies did not state any guiding principles, possibly because the computer-based intervention was used in a comparator arm (Barnett et al. 2007; Donohue et al. 2004; Lau-Barraco & Dunn 2008).

#### *Intervention - intensity of intervention*

In many studies, personalised feedback was made available on screen for a few minutes, and in some cases it was possible to print and take away. The campus-based interventions comprised longer sessions of up to three hours. Some studies allowed participants access to the intervention over a period of several weeks (Matano et al. 2007; Paschall et al. 2006), whilst others recommended revisiting the website to complete different sessions (Chiauzzi et al. 2005; Riper et al. 2008b). Two studies investigated multiple exposures to the intervention as part of their study design (these arms were combined for inclusion in the meta-analyses) (Barnett et al. 2007; Kypri et al. 2008).

## **Bias assessment**

Three studies made explicit reference to randomisation sequence generation and the procedure for allocating participants to groups. These studies were classified as having low risk of bias associated with allocation concealment (Kypri et al. 2004b; Kypri et al. 2008; Kypri & McAnally 2005). The remainder of studies were assessed as having unclear risk of bias, meaning there was insufficient information in the publication to judge this aspect of trial quality.

Twenty studies reported a sample size of less than 300 participants, six of which had less than 100 participants. The smallest sample size was 40, reported in two studies (Hester & Delaney 1997; Weitzel et al. 2007), whilst the largest was over 1,000 (Neumann et al. 2006).

## **Study outcomes**

A variety of outcomes were used to measure alcohol consumption. Most of the studies reported between one and four different drinking outcomes, whilst one study reported eight (Chiauzzi et al. 2005) and another reported ten (Matano et al. 2007) (see Table 2. Characteristics of included studies). Twelve studies measured short-term outcomes (less than 3 months), nine measured medium-term outcomes (3 to 6 months) and three measured long-term outcomes (longer than 6 months). The shortest length of follow-up was two weeks (Weitzel et al. 2007) and the longest was 12 months (Barnett et al. 2007; Kypri et al. 2008; Neumann et al. 2006).

### *Total alcohol consumption (quantity measure)*

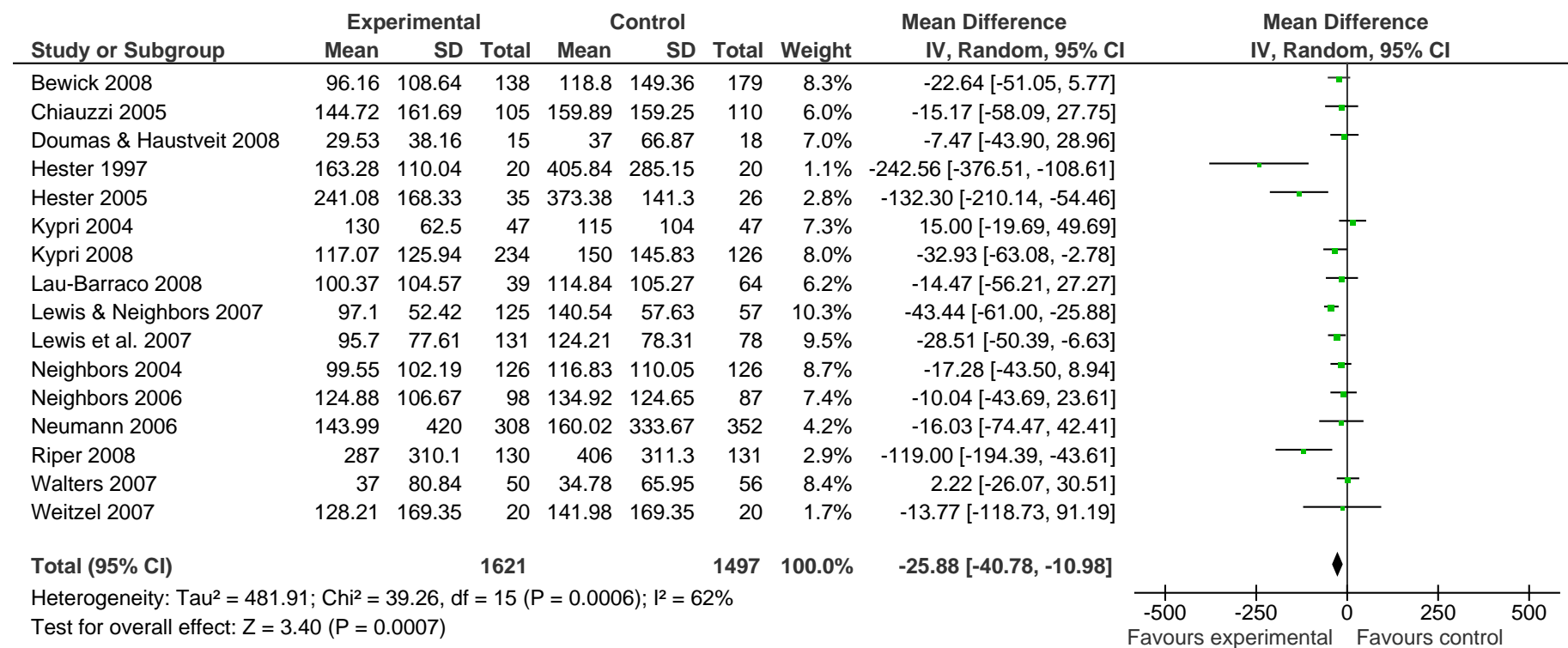
Nineteen studies measured the quantity of alcohol as actual or average drinks/units consumed within a given time frame. Missing data were obtained from two study authors

(Neumann et al. 2006; Walters et al. 2007). One study was excluded from the meta-analyses as it did not provide standard deviations, and contact details were not available for the study author (US thesis) (Hunt 2004). Fifteen studies appeared to have skewed data. Five of the 15 studies presented suitable measures of central tendency given the skewed distribution of the data: two provided transformed data (Hester et al. 2005; Walters et al. 2007) and three reported medians (Kypri et al. 2004b; Kypri et al. 2008; Neumann et al. 2006). Hence, a total 18 studies (10 of which were unadjusted for skewed data) were included in the meta-analyses for this outcome (analyses 1-2).

*Analysis 1: Computer-based intervention vs. minimally active comparator – grams/week*

The primary meta-analysis compared computer-based interventions with a minimally active comparator. It included 16 trials (nine unadjusted for skewed data) with a total of 3,118 participants. Participants receiving a computer-based intervention reduced the amount of alcohol consumed per week significantly more than those receiving the minimally active comparator (mean difference = -25.9 grams per week; 95% CI: -41 to -11). The mean difference was equal to 3.24 UK units of alcohol (where 1 UK unit = 8g ethanol). There was however, substantial heterogeneity between the findings of the trials, with an  $I^2$  value of 62%. This indicates that although participants in most studies appeared to benefit from the computer-based intervention, the estimated benefit varied substantially between the trials (see Figure 2).

**Figure 2. Analysis 1: Computer-based intervention vs. minimally active comparator – grams/week**

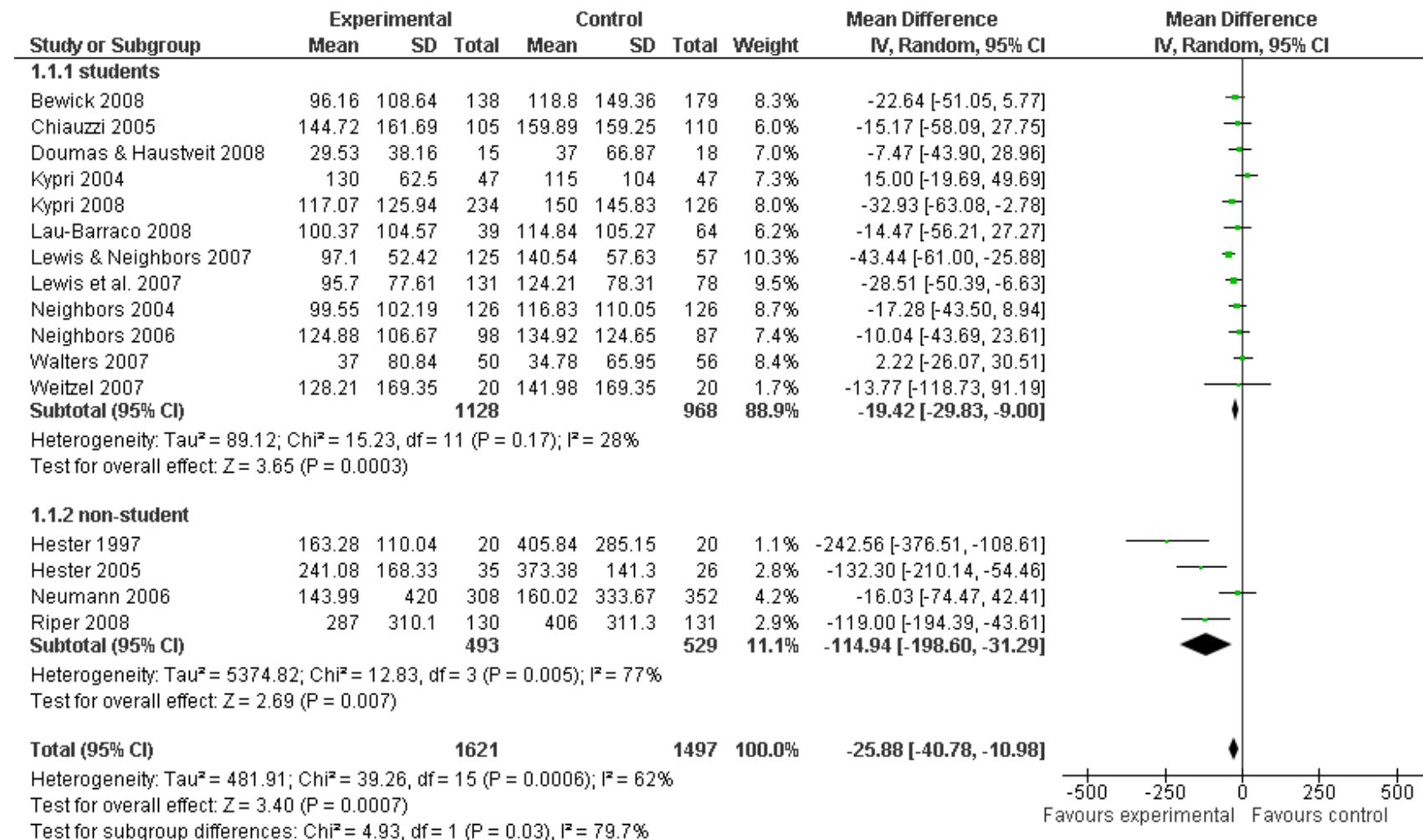


*Analysis 1.1: Subgroup analysis: students vs. non-students – grams/week*

The heterogeneity between the findings of the trials was explored in a subgroup analysis by population. The studies were separated into two groups: students and non-students (three studies in adult problem drinkers from the general population and one in emergency department attendees). The two groups were found to significantly differ from each other ( $p < 0.001$ ), suggesting a more pronounced effect in the non-student, adult population (see Figure 3). The heterogeneity was substantially reduced within the student subgroup ( $I^2 = 28\%$  for students,  $I^2 = 77\%$  for non-students) (see Figure 3).



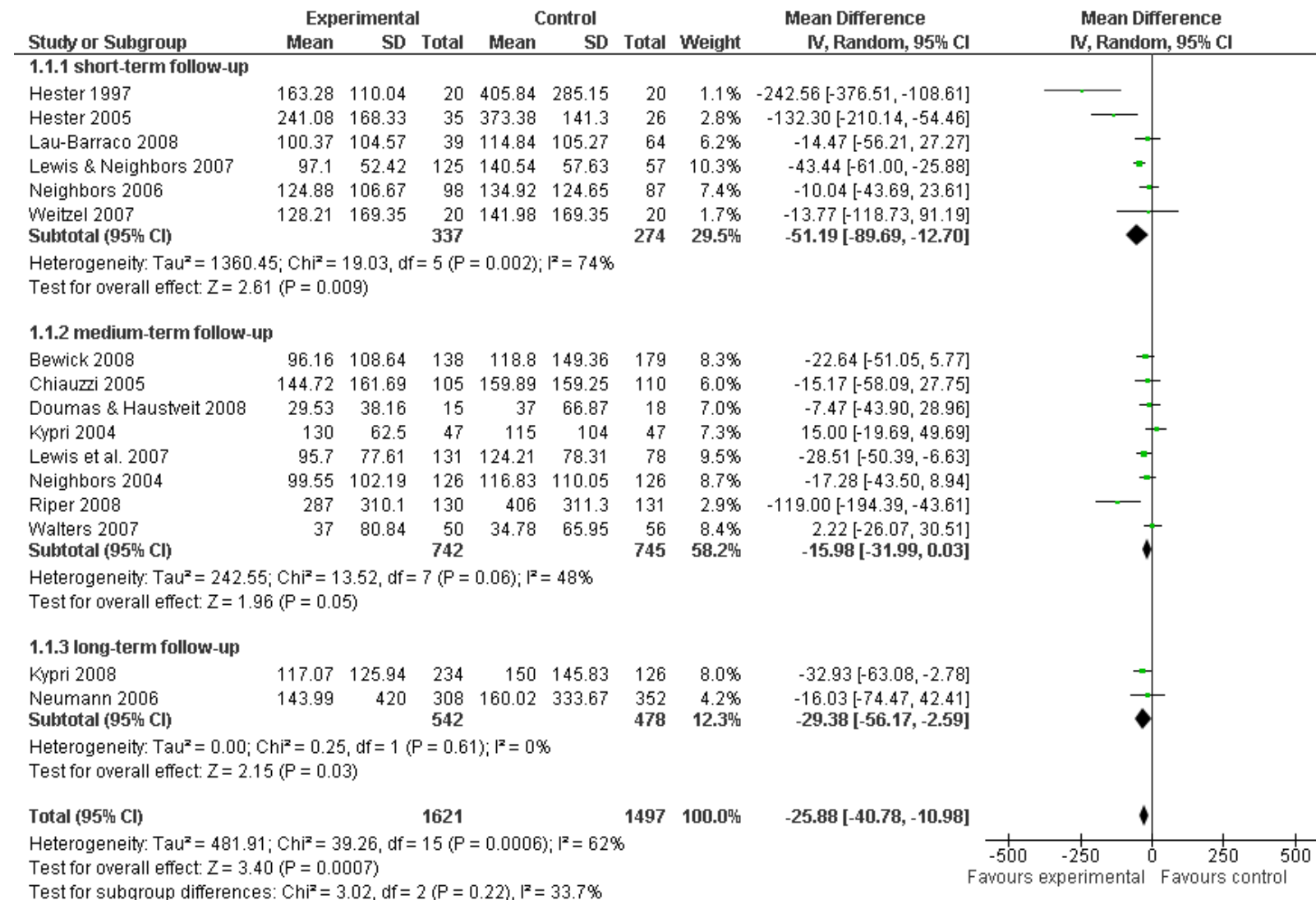
**Figure 3. Analysis 1.1: Subgroup analysis: students vs. non-students – grams/week**



*Analysis 1.2: Subgroup analysis: length of follow-up (all populations) – grams/week*

Heterogeneity was also explored in a subgroup analysis by length of follow-up. The studies were separated into three groups: short-term (less than 3 months), medium-term (3 to 6 months), and long-term (longer than 6 months). The three groups were found to significantly differ from each other ( $p < 0.001$ ). The heterogeneity remained in the short-term ( $I^2 = 74\%$ ) and medium-term ( $I^2 = 48\%$ ) groups, while no heterogeneity was observed between the two studies measuring long-term outcomes ( $I^2 = 0\%$ ) (see Figure 4).

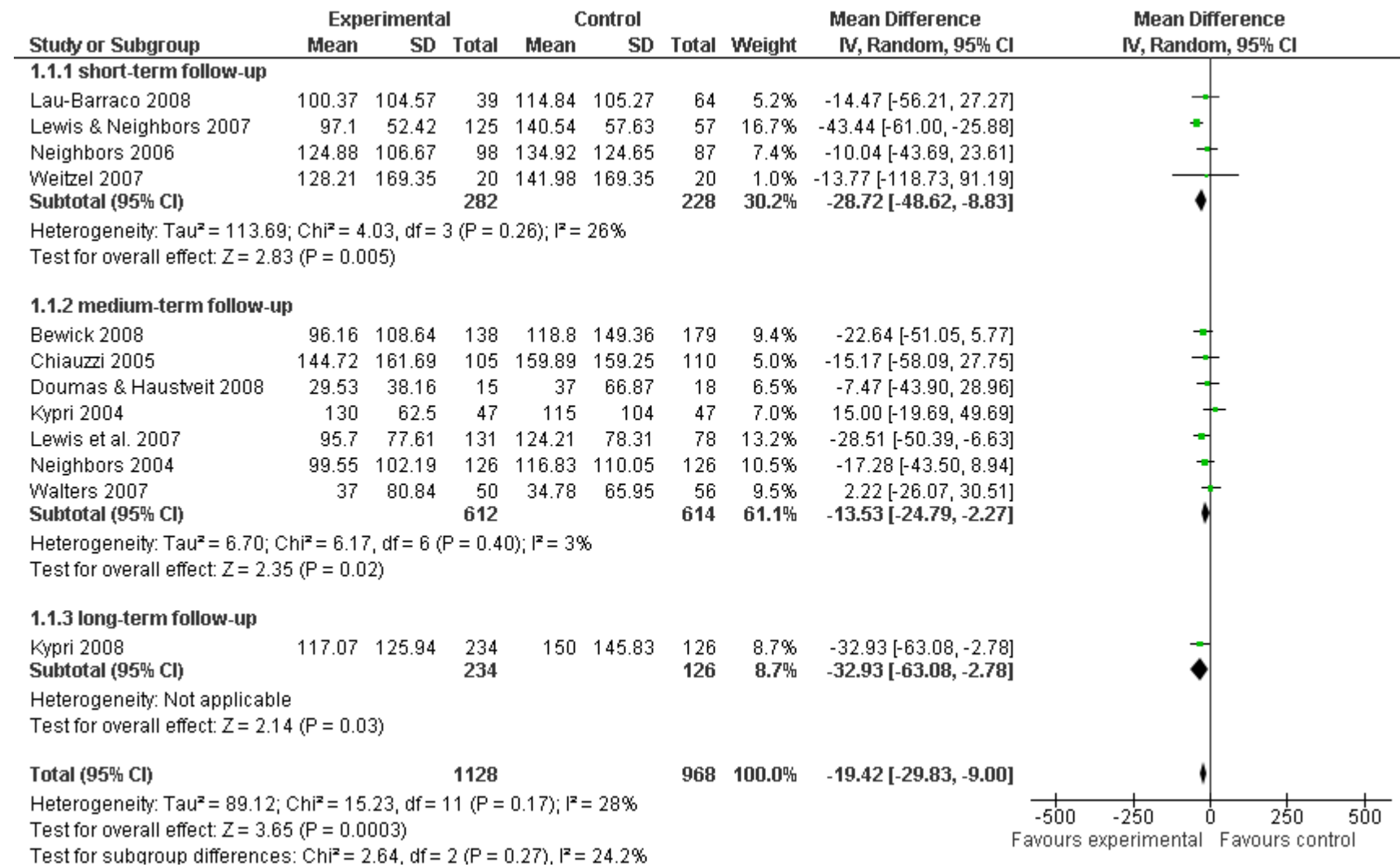
**Figure 4. Analysis 1.2: Subgroup analysis: length of follow-up (all populations) – grams/week**



*Analysis 1.3: Subgroup analysis: length of follow-up (students only) – grams/week*

Analysis 1.2 was repeated after removing studies of non-students. The three groups were no longer significantly different from each other. Heterogeneity was substantially reduced within each group ( $I^2 = 26\%$  for short-term,  $I^2 = 3\%$  for medium-term, N/A for long-term as only included one study) (see Figure 5).

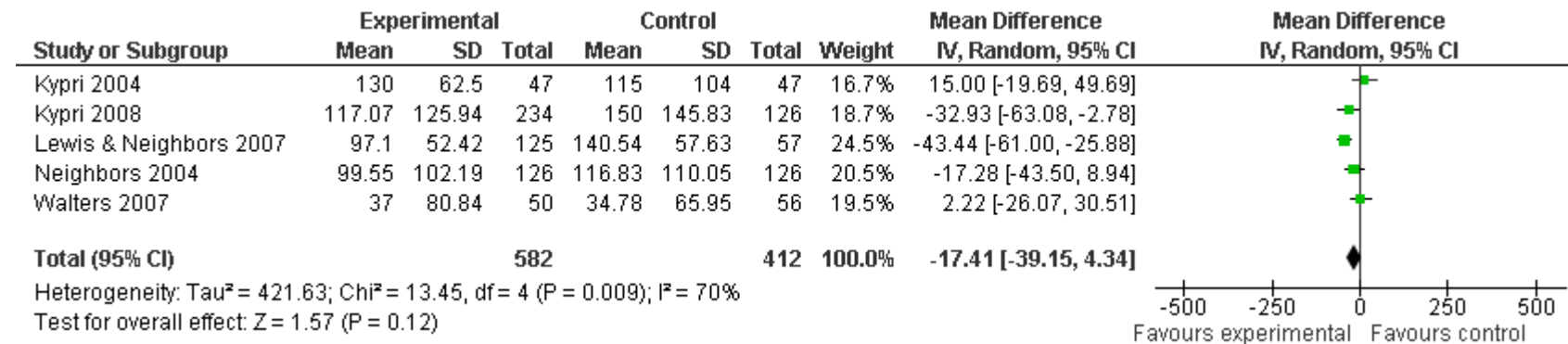
**Figure 5. Analysis 1.3: Subgroup analysis: length of follow-up (students only) – grams/week**



*Analysis 1.4: Sensitivity analysis (students only): studies presenting suitable measures of central tendency given the distribution of the data – grams/week*

This analysis included two studies presenting medians (Kypri et al. 2004b; Kypri et al. 2008), one study that presented back-transformed data (Walters et al. 2007), and two studies that reported no evidence of skew (Lewis & Neighbors 2007; Neighbors et al. 2004). These five studies in student populations (994 participants) found no significant difference between computer-based interventions and minimally active comparator groups in alcohol consumed per week (see Figure 6). This analysis was not possible in the non-student adult population due to the small number of studies.

**Figure 6. Analysis 1.4: Sensitivity analysis (students only): studies presenting suitable measures of central tendency given the distribution of the data – grams/week**

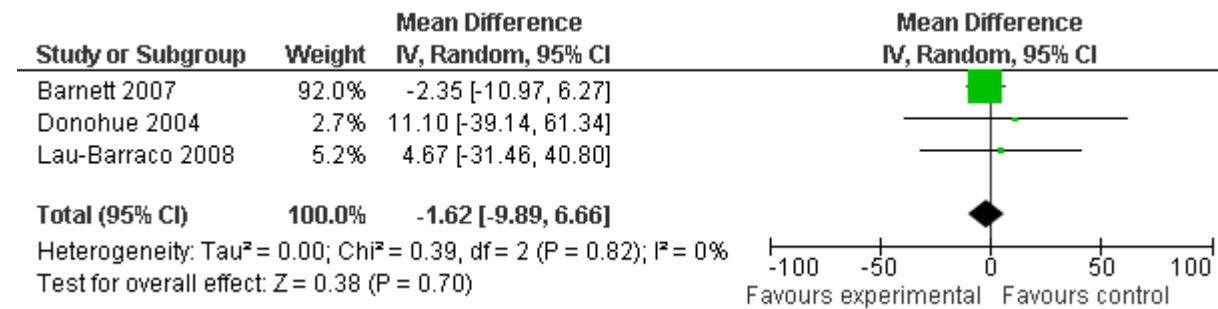


*Analysis 2: Computer-based intervention vs. active comparator – grams/week*

Three studies (two unadjusted for skewed data), including 457 student participants, compared a computer-based intervention with an active comparator (Barnett et al. 2007; Donohue et al. 2004; Lau-Barraco & Dunn 2008). There was no significant difference between participants receiving a computer-based intervention and an active comparator group in alcohol consumed per week. There was no heterogeneity observed between the findings of the trials ( $I^2 = 0\%$ ). However, the analysis was heavily weighted by one particular study (Barnett et al. 2007) (see Figure 7).



**Figure 7. Analysis 2: Computer-based intervention vs. active comparator – grams/week**



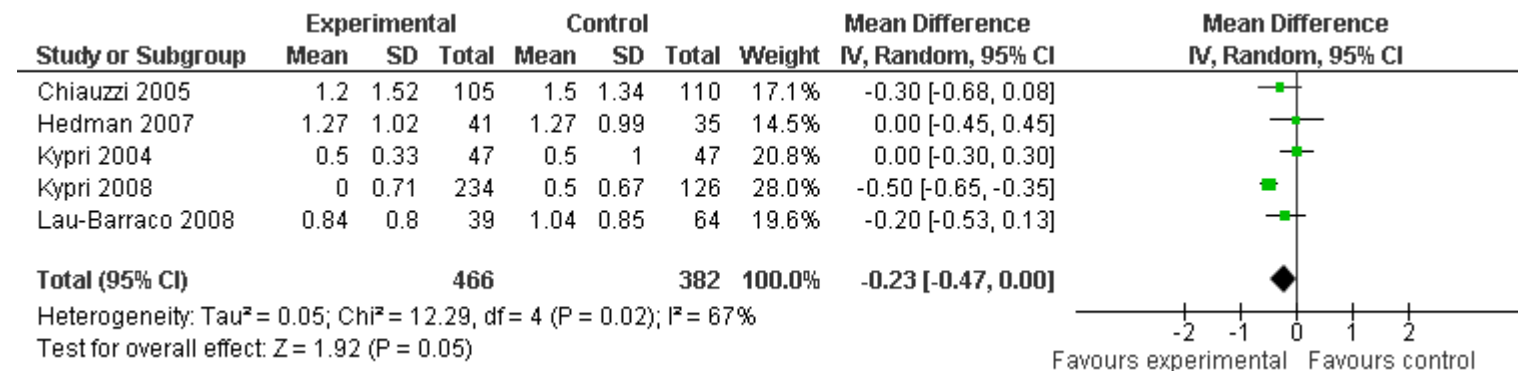
### *Binge drinking (frequency measure)*

Eight studies measured frequency of binge (or heavy episodic) drinking days or episodes within a given time frame. Two studies were excluded from analyses for reporting the proportion of binge drinking days (Hunt 2004) and frequency of heavy drinking as a categorical variable (Paschall et al. 2006). All of the studies reporting this outcome demonstrated a skewed distribution at furthest point of follow-up. Two studies accounted for this by presenting medians (Kypri et al. 2004b; Kypri et al. 2008).

### *Analysis 3: Computer-based intervention vs. minimally active comparator – binge frequency/week*

This analysis included five trials (three unadjusted for skewed data) with a total of 848 student participants (Chiauzzi et al. 2005; Hedman 2007; Kypri et al. 2004b; Kypri et al. 2008; Lau-Barraco & Dunn 2008). Participants receiving a computer-based intervention appeared to reduce their frequency of binge drinking compared with those receiving a minimally active comparator (mean difference = -0.23 days per week; 95% CI: -0.47, 0.00;  $p=0.05$ ). This finding was of borderline significance. There was substantial heterogeneity between the findings of the trials, with an  $I^2$  value of 67% (see Figure 8).

**Figure 8. Analysis 3: Computer-based intervention vs. minimally active comparator – binge frequency/week**



#### *Analysis 4: Computer-based intervention vs. active comparator – binge frequency/week*

There were only two studies that made this comparison (Barnett et al. 2007; Lau-Barraco & Dunn 2008) and so the findings were not pooled in a meta-analysis. Both studies reported no significant difference in binge frequency between the intervention and an active comparator group.

### **Discussion**

The data identified by this review suggested that computer-based interventions were more effective than minimally active comparator groups at reducing alcohol consumed per week in both student and non-student adult populations. A mean difference of 26 grams of alcohol per week was found between computer-based interventions and minimally active comparator groups. This is equivalent to around three UK units of alcohol, e.g. one large glass of wine, one pint of beer, or two large shots of spirits. This difference is of similar magnitude to that reported in a Cochrane review of hazardous and harmful drinkers in primary care, where participants receiving brief interventions in-person reduced their alcohol intake significantly more than those in the control condition (difference of 38 grams per week; 22 trials with 7,619 participants) (Kaner et al. 2007). The effectiveness of computer-based interventions in student populations was less pronounced than in non-student populations and diluted the overall reduction in alcohol consumption (see Figure 3). The difference in baseline alcohol consumption (or baseline risk) between students and non-students may explain the variation in the size of effect between the population groups. It was possible that non-students were consuming greater amounts of alcohol at baseline than students and therefore had greater capacity for reducing their intake. An investigation of the relationship between baseline risk and effect was planned for further analyses; however, this was not pursued given the methodological limitations of the data (discussed below). There may also have been differences in baseline risk among the non-

student samples, explaining the substantial heterogeneity among this subgroup. It would be advisable for future reviews to separate these studies by population or setting.

The content of the interventions may also have influenced the size of effect in population groups. Interventions aimed at non-student populations were more extensive and included a wider range of behaviour change techniques, such as goal-setting, self-monitoring and relapse prevention (Abraham & Michie 2008). A recent review of Internet-based interventions promoting a range of health behaviours found those interventions with greater theoretical grounding and a wider range of behaviour change techniques to have more of an impact on behaviour (Webb et al. 2010). Extended brief interventions delivered in-person in primary care were found to be more effective at reducing alcohol intake than minimal brief interventions; however, this finding was of marginal significance (Kaner et al. 2007). Computer-based interventions are complex interventions, where a number of components may act both independently and inter-dependently to change behaviour (Medical Research Council 2000). There may be certain 'active ingredients' that determine their effectiveness in addition to recognised behaviour change techniques. One of the previous reviews in this field investigated several treatment moderators of effect of computer-based alcohol and tobacco interventions and found them to have no significant impact on outcomes; these included normative feedback, chat function, entertainment feature, relapse prevention module, exposure to intervention, and location of access (Rooke et al. 2010). The 'active ingredients' of effective brief interventions remain undetermined, as does the suitability of a 'one size fits all' approach; these have been noted as key directions for future research (Kaner 2010). The user's perspective is essential in determining the features of interventions that people find most helpful and in developing services best suited to their needs (see Chapter 6).

The finding that computer-based interventions were effective in student populations echoes that of previous reviews in this field (Carey et al. 2009; Elliott et al. 2008; Rooke et al. 2010). This review, however, highlighted that most studies used an unsuitable measure of central tendency (i.e. arithmetic mean) given the skewed distribution of the data. In large samples this is not a problem as the “means of random samples from any distribution will themselves have a normal distribution” p.298 (Altman & Bland 1995); this is known as the central limit theorem (Altman & Bland 1995). However, in a skewed distribution where sample sizes are small or modest, the arithmetic mean and median do not approximate each other as, extreme values affect the arithmetic mean but not the median. In this scenario, measures of central tendency that account for the skewed distribution of the data should be used, such as medians, log-transformations or geometric means (back-transformations). A sensitivity analysis of studies that presented suitable measures of central tendency for the distribution of the data found there was no longer a difference in alcohol consumed per week by students in the intervention and minimally active comparator groups. Comparing values that do not accurately describe the data may result in the wrong conclusion. Advocating the use of suitable measures of central tendency according to the distribution of data is an important implication for future research in this field.

Some researchers have highlighted that alcohol consumption is typically measured as count rather than continuous data, e.g. number of drinks consumed within a given time frame (Horton et al. 2007; Kypri 2007). As such, analyses based on distributions for discrete data should be conducted, such as the negative binomial distribution (Kypri 2007). This would have been possible with the collection of individual patient data from all eligible studies, but was not pursued due to the time constraints of this project. Most of the studies identified by this review treated the data as continuous and provided arithmetic means, allowing for the conduct of meta-analyses of mean differences. However, three

well-conducted studies presented medians (Kypri et al. 2004b; Kypri et al. 2008; Neumann et al. 2006) which presented a problem when pooling the data. To prevent the exclusion of these studies the median was used to estimate the mean and the range was used to generate an estimated standard deviation (Hozo et al. 2005). Estimating the sample mean in this way may have introduced errors; however, an estimation of a correct statistic was considered preferable to the exclusion of these studies from the meta-analyses. At present, there is no consensus on how best to pool different measures of central tendency in meta-analyses (Deeks et al. 2009).

Another challenge with pooling the data was that the study authors investigated several different drinking outcomes, with no one outcome recognised as a gold-standard (discussed further in Chapter 4). Alcohol consumption can be assessed by different measures (e.g. daily drinking questionnaire, weekly recall, timeline follow-back calendar) and in different formats (e.g. in-person, paper-based or computer-based) to calculate a variety of outcomes (e.g. number of drinking days, days drinking above recommended limits, largest amount drunk on a single occasion). As such, several different approaches were used in the included studies, with five studies excluded from the meta-analyses as they did not measure the outcomes chosen for this review. This review investigated the effectiveness of computer-based interventions with two specific drinking outcomes: total consumption and binge frequency. These reflect the two patterns of drinking that are thought to increase the likelihood of alcohol-related harm, i.e. chronic drinking and binge drinking (as mentioned in Chapter 1). The use of mean differences provides a meaningful interpretation of the pooled data, i.e. grams of alcohol consumed per week and frequency of binge drinking episodes per week. Presenting alcohol consumption in grams allows for international comparisons with other studies. The use of standard outcomes for different patterns of drinking would help future reviews incorporate as much of the literature as possible. A further consideration for the online evaluation of Internet-based interventions

is that a measure cannot be assumed to retain its psychometric properties when transferred online. This issue is explored further in Chapters 3 and 4 with the development on an online measure of alcohol consumption for use in the DYD online trial.

This review considered allocation concealment as a potential source of bias. Only three studies were assessed as having low risk of bias (Kypri et al. 2004b; Kypri et al. 2008; Kypri & McAnally 2005), while the other studies provided insufficient information to make the assessment. It is likely that many studies assessed as 'unclear' were poorly reported rather than poorly designed, for example, those conducted over the Internet in their entirety would consequently have concealed allocation to randomised group. Other sources of bias in trial design include inadequate sequence generation and blinding, incomplete outcome data (explored further in Chapter 5) and selective reporting (Higgins & Altman 2009). Many of these are most applicable to conventional drug trials, and problems occur when applying them to trials of computer-based behavioural interventions, particularly those conducted online. In an online trial it is likely that sequence generation and allocation concealment will have been performed by a computer in a fully automated process. Blinding of participants and study personnel is not truly possible with behavioural interventions where some participants receive access to an intervention and others do not. Also, blinding of outcome assessors may not be relevant in an online trial where participants complete follow-up questionnaires from a remote location over the Internet. Future trial designs and publications would benefit from explicit reference to these factors and attempts to identify other sources of bias unique to online trials and computer-based interventions, such as multiple trial registrations. Incomplete outcome data is a particular concern in online trials (Eysenbach 2005). The use of incentives to reduce attrition in the DYD online trial is investigated in Chapter 5.



Publication bias was not investigated in a funnel plot due to the limitations of this approach. Differences in the methodological quality of studies can result in funnel plot asymmetry and thus incorrectly indicate the presence of publication bias (Sterne et al. 2009). Publication bias was not anticipated to be a particular concern in this review, unlike in studies of interventions with commercial interest, such as expensive new pharmaceuticals. Studies of Internet-based interventions for reducing alcohol intake are also an emerging field of research and so the 'file drawer problem', where studies with negative findings are not published, may not be as apparent. Unpublished data were sought in the form of theses and conference proceedings. Had time permitted, further attempts to identify unpublished data would have included contacting experts in the field and searching trial registers for ongoing trials.

## ***Conclusion***

The findings from these analyses suggest that computer-based interventions are effective at reducing total weekly consumption and frequency of binge drinking in adults when compared with minimally active comparator groups. However, the findings remain tentative because of methodological weaknesses in the studies, such as the use of unsuitable measures of central tendency, small sample sizes, short-term follow-up, and insufficient information to judge potential sources of bias. In identifying these limitations with the existing literature, it is hoped that future research will be of greater methodological rigour. Further studies should also address the gaps in the evidence base, with an urgent need for studies in non-student adult populations and comparisons of computer-based interventions with active comparator groups. Evidence from these trials is needed before computer-based interventions are advocated for reducing alcohol consumption, and before they can viably increase the availability of services for hazardous and harmful drinkers.

The following chapter (Chapter 3) reports on an online trial of an Internet-based intervention called 'Down Your Drink' (DYD) that has been published since the completion of this review. The DYD trial addressed many of the limitations identified above. It included adults from the general population, recruited a large sample with long-term follow-up and demonstrated high external validity by recruiting people looking for help over the Internet to reduce their drinking. It also reported on aspects of trial quality that may introduce bias and addressed the skewed distribution of the data by reporting geometric means (back transformed data). This trial provided the context for further exploration of the Internet as a means delivering and evaluating interventions for reducing alcohol intake.

## Chapter 3: The Down Your Drink randomised controlled trial

### ***Chapter overview***

The Down Your Drink online trial addressed many of the limitations of studies conducted in this field, as highlighted by the systematic review in Chapter 2. It evaluated an Internet-based intervention (DYD intervention) aimed at reducing alcohol intake in adults from the general population. The use of the Internet to evaluate DYD allowed for the recruitment of a large sample size with high generalisability to the population of interest, i.e. people seeking help or information with their drinking online. However, several methodological challenges arose when conducting the DYD trial over the Internet. The aim of this chapter is to describe the development of the Down Your Drink Internet-based intervention and the online randomised controlled trial that evaluated its effectiveness. It provides the reader with the background necessary for understanding the methodological challenges explored in the following chapters of this thesis. These included the creation and validation of an online measure of alcohol intake for use in the DYD trial (Chapter 4); an investigation into the impact of incentives on improving follow-up rates among DYD trial participants (Chapter 5); and an exploration of DYD participant experience of using an Internet-based intervention and taking part in an online trial (Chapter 6).

### ***The DYD intervention***

Down Your Drink is an Internet-based intervention aimed to help adults from the general population to reduce their drinking. The website was first launched in October 2001, where it was modelled on a self-help manual of the same name (Linke et al. 2004). It originally used the 'stages of change' psychological model of behaviour change (Prochaska & DiClemente 1992) to organise the components of the intervention. Within

this model it used approaches known to be effective at motivating, eliciting and maintaining change, including motivational enhancement (Miller et al. 1992) (see Box 1), cognitive behavioural therapy (Kadden et al. 1992) (see Box 1), and relapse prevention (Marlatt & Gordon 1985). This original version of the website consisted of six modules that required completion at weekly intervals. The website also included a number of interactive features, such as a drinking diary, blood alcohol level calculator, 'thinking drinking log' of answers to exercises, and email or mobile phone text message tips for controlled-drinking (these features are described below) (Linke et al. 2004). A cohort study of 10,000 visitors to this original version of the DYD intervention website found a reduction in alcohol-related problems, dependency and mental health symptoms (Linke et al. 2007). This led to a successful application to the Medical Research Council (MRC) National Prevention Research Initiative (NPRI) for a Phase II pilot trial including extensive development of the original intervention and optimisation of the trial parameters, and a Phase III RCT of the DYD intervention website (outlined below) (Medical Research Council 2000).

Prior to the Phase II pilot trial, the original DYD intervention website underwent extensive redevelopment. One substantial change was removing the 6-week modular program and the associated restrictions on access. This was in accordance with user feedback that this prescribed use of the website did not reflect the way in which people generally navigate freely through the Internet (Linke et al. 2008). Another major alteration to the intervention was removing the 'stages of change' structure to the content, in-line with recent challenges to the model's validity (West 2005).

The updated DYD intervention website consists of an extensive behaviour change program based on the principles of motivational interviewing, cognitive behaviour therapy, behavioural self-control, and relapse prevention (Linke et al. 2008). It is presented in three phases: Phase 1 'It's up to you', helps people reach high-quality decisions about whether

to change their drinking; Phase 2 'Making the change', plans a specific change and provides the tools needed to cut down; Phase 3 'Keeping on track', provides support with maintaining change and avoiding relapse. These phases can be accessed in any order, depending on the needs of the individual. The intervention also contains a number of 'e-tools', central to which is the 'Drinking Episode Diary'. The diary allows users to record their alcohol consumption and their thoughts and feelings surrounding each drinking episode. It includes a search function to help people analyse their drinking; for example, entering the term 'sad' would identify all the diary entries in which the user had reported this emotion and the situations that had led them to feel this way. The Drinking Episode Diary also calculates the cost and calories related to consumption each day. Other interactive tools in the DYD intervention include:

- Thinking Drinking Record: A log of answers to the exercises throughout the programme, which are available for review. The exercises can be repeated any number of times.
- Tips from the DYD Team: Daily emails from the Down Your Drink team providing tips on cutting down (these can be switched on or off).
- Blood Alcohol Level Calculator: Estimates the concentration of alcohol in the blood based on the amount drunk in a given time period. It gives recommendations on when it is safe to drive after a particular drinking session.
- Unit Counter: Converts drinks into units of alcohol. It also provides the formula for manual calculation.
- Alcohol and Relationships: Provides a visual display of how someone's drinking might be influenced by others around them.

## ***DYD trial design***

The aim of the DYD trial was:

“to compare the relative effectiveness and cost-effectiveness of an online, psychologically enhanced, interactive computer-based intervention (Down Your Drink) in reducing alcohol consumption with a flat, text-based information website in hazardous and harmful drinkers.” p.2 (Wallace et al. 2011).

The experimental arms were described as constituting different areas of the DYD website and, as such, were both referred to as DYD. Presenting them in the same format aimed to maximise equipoise. The DYD control website was similar to the alcohol information websites currently available over the Internet that outline the harms of hazardous and harmful drinking, but contained minimal interactivity.

The trial was conducted in three phases:

Phase 1 (pilot trial):

- Participants were recruited between February 2007 and October 2007;
- Follow-up was requested at 1 and 3 months;
- Participants were not screened for hazardous drinking;
- The pilot phase aimed to optimise the trial parameters of recruitment, randomisation, retention to both the intervention and trial, and data quality (Murray et al. 2009). Efforts to address some of the methodological challenges introduced by online trials were pursued in Chapters 4 and 5.

Phase 2 (main trial):

- Participants were recruited between October 2007 – August 2008;
- Follow-up was requested at 3 and 12 months;
- Participants were screened for hazardous drinking using the AUDIT-C (outlined below).

Phase 3 (main trial extension):

- Participants were recruited between September 2008 and May 2009;
- Follow-up was requested at 3 months;
- Participants were screened for hazardous drinking;
- The decision to extend the main trial was made on ethical grounds - to maintain access to a unique resource that addressed an otherwise unmet need (discussed below and in Chapter 6). After recruiting for this phase of the trial, the DYD control website was made available to all new registrants and was replaced with the DYD intervention website once data collection was complete.

## **Recruitment**

The trial was conducted entirely online through the DYD website ([www.downyourdrink.org.uk](http://www.downyourdrink.org.uk)), including recruitment, consent, baseline data collection, randomisation and follow-up. The DYD website was identified through search engines or links from other websites. Alcohol Concern, the national agency on alcohol misuse, provided a link to the DYD website from their homepage for the duration of the trial. Alcohol Concern often comments on alcohol-related news stories on the BBC news website, where a link to Alcohol Concern's homepage is provided. Other popular websites providing a link to DYD included Patient.co.uk, a health information website, and Drinkaware.co.uk, a UK charity that provides information about alcohol consumption, funded by the alcohol industry. There was no further promotion of the Down Your Drink website.

The DYD homepage describes the website as “designed to help you work out whether you're drinking too much, and if so, what you can do about it.” (Down Your Drink website 2011). It invites visitors to find out if they are drinking too much by pressing a button. This

takes them to a screening test for hazardous drinking, the 3-item Alcohol Use Disorders Identification Test (AUDIT-C), which consists of the first three questions on the AUDIT (Bush et al. 1998) (outlined below). For the pilot phase of the trial, all visitors were invited to participate regardless of their level of drinking. The AUDIT-C scores of these participants were compared with their past-week alcohol consumption (the primary outcome, outlined below and in Chapter 4) to determine a cut-off score that represented the weekly safe drinking limits (see Chapter 1). This was determined as a score of 5 or more for both men and women. This cut-off score was then used to screen people for hazardous and harmful drinking in phases 2 and 3 of the DYD trial. During these phases people scoring 5 or more on the AUDIT-C received the following feedback:

- Thank you for taking the test, your drinking pattern indicates a possible increased risk of alcohol affecting your health.
- The new Down Your Drink website is packed full of useful information designed to help people drink alcohol more safely and improve their general health and well-being.

As mentioned in Chapter 1, screening and feedback on risk of harm is the simplest form of brief intervention and known to be effective at reducing alcohol consumption. The potential impact of this screening and feedback on the results of the DYD trial is considered below and in Chapter 6. Participants in both arms of the DYD trial received this feedback before entering the trial, and as such, the potential impact on behaviour is independent of the intervention or control condition.

Participants were then informed that access to the DYD website was restricted to people consenting to take part in a randomised controlled trial. The way in which people self-recruited to the DYD trial, i.e. searching online for help or information on their drinking and consenting to take part in a trial in order to access help, suggests some motivation to address their drinking behaviour. As mentioned in Chapter 1 in relation to treatment



seekers, this has important implications for interpreting the findings of the trial and is discussed further in this chapter and in Chapter 6. The subsequent web pages presented the trial participant information, followed by an online consent form. Eligible participants were adults (aged 18 or over), did not suffer from serious mental health problems and were fluent in English. Having submitted the online consent form, participants were asked to create a login to the website which would allow them to access the site again at any point in time, as frequently as they wished. Participants were then asked for some demographic information, details on how they found the Down Your Drink site and whether they had viewed other alcohol-related websites before entering the trial. Offline contact details were an optional request that allowed for additional follow-up prompts by the research team (where email prompts were primarily used). At this point an email was sent to the participant to validate their email address. They were then instructed to follow a hyperlink from the email back to the DYD website to complete baseline questionnaires.

### **Outcome measures and data collection**

On returning to the website, all participants were asked to complete the EQ-5D index and visual analogue scale (VAS) (Rabin & de Charro 2001), used for the economic analysis. This was followed by the primary outcome of total past-week alcohol consumption, measured by the TOT-AL (Khadjesari et al. 2009) (see Chapter 4). Past-week alcohol intake is a measure of consumption used by many of the studies in this field (as demonstrated in the systematic review in Chapter 2). Yet unlike many of the studies in the systematic review, the DYD trial required an online outcome measure. One of the methodological challenges of conducting online trials is that a measure transferred from one modality to another does not necessarily retain its psychometric properties (Buchanan 2002; Miller et al. 2002; Ritter et al. 2004; Wantland et al. 2004). This led to the development of the TOT-AL and an investigation into its test re-test reliability and

comparability with the in-person approach to eliciting past-week alcohol consumption (see Chapter 4). The TOT-AL was designed to calculate units per week (the primary outcome of the DYD trial), but in collecting beverage-specific consumption over the past seven days it also allowed for the assessment of number of drinking days, days drinking above recommended safe limits and number of binge drinking occasions, each measuring different patterns of drinking (see Chapter 4 for further discussion). Assessment measures used to determine alcohol consumption are known to be reactive, i.e. lead to a reduction in drinking (Carey et al. 2006; Kypri et al. 2007; McCambridge 2009; McCambridge & Day 2008) (discussed further in Chapter 4). It is therefore possible that trials assessing drinking outcomes under-estimate treatment effects by producing an effect of their own. As with screening, the potential impact of assessment on drinking behaviour should be considered when interpreting the findings of the DYD trial (discussed below and in Chapter 6).

Participants were asked to rate their confidence in their ability to reduce their drinking (i.e. self-efficacy), from “not at all confident” to “completely confident” on a five-point scale. This was followed by a rating of their intention to reduce their drinking over the next three months, from having “no intention” to being “completely committed”, also on a five-point scale. Self-efficacy and intention are hypothesised antecedents to change in psychological theories of behaviour change (Ajzen 1988; Ajzen 1991; Bandura 1986; Bandura 1997).

Participants were randomised to one of four secondary outcome measures in an attempt to reduce response burden. Secondary outcome measures were the Alcohol Use Disorders Identification Test (AUDIT), a validated screening test for hazardous and harmful drinking (Babor et al. 2001); Alcohol Problems Questionnaire (APQ) (Williams & Drummond 1994); Leeds Dependence Questionnaire (LDQ) (Raistrick et al. 1994); and the

Clinical Outcomes for Routine Evaluation (CORE-OM and CORE-10) measure of mental health (Connell & Barkham 2007). After completion of baseline measures, participants were randomised to one of the two different areas of the DYD website (DYD intervention and DYD control). They were given unlimited access to their allocated arm from any setting with Internet access. Participants were followed up by email prompt at one and three months (pilot phase), three and twelve months (main phase), and three months (main trial extension). Reminder emails were sent at weekly intervals to those participants not responding, up to a maximum of two further emails containing a hyperlink to the outcome measures.

## ***Trial results***

### **Recruitment and retention**

The three phases of the trial (i.e. pilot, main trial and main trial extension) were pooled for analyses due to their similarities (Wallace et al. 2011). Participants self-recruited at a steady rate of around 65 per week throughout the duration of the trial. A total of 7,935 people completed baseline measures and were randomised to one of the experimental arms. These high and consistent rates of recruitment point to the ease in which large numbers of participants can be easily recruited over the Internet and data can be instantaneously collected. They also suggest an otherwise unmet need among the general population for help to reduce their drinking (explored in Chapter 6).

At three months, follow-up (i.e. completion of the TOT-AL) was 40% in the intervention group and 49% in the control group. These low rates of follow-up are a common occurrence in online trials (Eysenbach 2005), and increase the possibility of non-response bias (as discussed in Chapter 5). The DYD team considered a number of strategies for improving follow-up rates in addition to the email reminders. Postal and telephone

reminders were used with a subset of non-responding participants who provided these optional contact details in the pilot study. These efforts had a small impact on improving response (i.e. 3%) and were extremely labour intensive; as such, they were not pursued in the main trial (Murray et al. 2009). Many of the participants contacted over the telephone appeared uncomfortable receiving a call from a researcher about the DYD trial and were quick to end the call. There may have been a number of reasons why, for example, if they had been busy, had forgotten about entering the DYD trial, or if they had not wanted anyone to overhear the call. The anonymity provided by the online setting of the DYD trial was found to be important to participants looking for help to reduce their drinking and may explain why these telephone prompts were not welcomed (as demonstrated in Chapter 6).

In a further attempt to improve follow-up rates and maintain the anonymity of participants, this thesis explores the use of incentives at improving follow-up in the DYD trial through two sequential RCTs (see Chapter 5).

Differential follow-up between experimental groups was observed at each follow-up time point, with a greater number of participants responding in the control group. This difference has been observed in previous trials of brief interventions with hazardous drinkers, but to a lesser extent (Kaner et al. 2007). Differential follow-up is a concern as it may undermine randomisation to create systematic differences between experimental groups (Doody et al. 2003). The DYD research team hypothesised that participants in the control group may be more likely to complete the assessment measures as they offer an opportunity to reflect on their drinking, whereas the participants in the intervention group have already had this opportunity through access to the various interactive tools. Qualitative interviews with DYD participants confirmed this hypothesis, with participants viewing the assessment procedures as part of the DYD programme (see Chapter 6).

## **Baseline characteristics**

Participants had a mean age of 38 years (SD 11), and included slightly more women than men (57%). The majority of participants were 'White British' (84%) and living in the UK (88%), with the remaining participants from 73 different countries. Many participants were married or in a long-term relationship (62%) and half had children (52%). Around half were educated to degree level and above (52%). Participants were in good health, indicated by an average EQ-5D index score of 0.84 (SD 0.19) and VAS score of 72 (SD 20). Participants were drinking an average of 46 (geometric mean) (SD 31.2) units per week (1 UK unit = 8 g ethanol). The average number of drinking days was 5 (SD 2), with participants drinking above recommended daily limits an average of 4.8 days per week. The average number of days binge drinking was 3.6 (SD 2) and the average maximum number of units consumed on one day in the past week was 15.8 (SD 10). DYD trial participants therefore display both chronic and binge drinking patterns of alcohol consumption. Participants reported medium levels of confidence in changing their drinking behaviour (mean 2.8, SD 1.6) and slightly higher intentions (mean 3.8, SD 1.1).

The average AUDIT score was 19 (SD 7). The World Health Organisation (WHO) advocates simple advice plus brief counselling and continued monitoring for people scoring 16-19 on the AUDIT (Babor et al. 2001). This finding suggests that DYD was attracting people most likely to benefit from an extended brief intervention. Participants reported experiencing several alcohol-related problems on the APQ (mean 7 (SD 4)) and low to moderate levels of dependence, with an average score of 9 (SD 6) on the LDQ (Raistrick et al. 1994). The mental health of DYD trial participants was generally good (mean CORE-OM score 1.3 (SD 0.7) and mean CORE-10 score 16.5 (SD 5)).

DYD participants displayed characteristics that were largely similar to the participants in the other general population studies included in the systematic review (Chapter 2). Similar

to DYD participants, around half of the participants from the other general population studies were female: 49% (Riper et al. 2008b), 48% (Hester et al. 2005), 40% (Hester & Delaney 1997); had an average age of 46 (Riper et al. 2008b), 45 (Hester et al. 2005), and 36 (Hester & Delaney 1997); were mostly Caucasian: 79% (Hester et al. 2005), 70% (Hester & Delaney 1997); and were consuming an average of 44 units per week (55 UK units; arithmetic mean) (Riper et al. 2008b), 6 drinks (standard ethanol content) per day (arithmetic mean) (Hester et al. 2005); and 39 drinks (standard ethanol content) per week (arithmetic mean) (Hester & Delaney 1997). The characteristics of these general population samples receiving computer-based interventions seem to represent a population of alcohol misusers not previously captured in research of conventional non-treatment seeking and treatment seeking populations receiving in-person interventions. Compared with studies of hazardous drinkers identified opportunistically in primary care (Kaner et al. 2007), there was a greater proportion of women in the DYD trial (57% vs. 30%), a slightly larger proportion of 'White British' participants (85% vs. 70%), and similar, although slightly higher, baseline consumption (46 vs. 39 units per week) (Kaner et al. 2007). Compared with a trial of treatment-seeking individuals (UKATT Research Team 2005b), DYD trial participants consisted of more women (57% vs. 26%), a slightly smaller proportion of 'White British' participants (85% vs. 96%), and a greater proportion of participants educated to degree level or above (52% vs. 10%). DYD participants were drinking less than these treatment seekers (46 units per week vs. 27 units per drinking day), they were also of better general health (EQ-5D score 0.84 vs. 0.57), displayed lower levels of dependence (LDQ score 9 vs. 17 (moderate to high dependence)), and experienced fewer alcohol-related problems (APQ score 7 vs. 12.3) (UKATT Research Team 2005b).

## **Website usage**

Those participants with access to DYD intervention made an average of 2.33 (SD 3.63) visits to the site and had downloaded an average of 67 (SD 79) pages one month after recruitment. Participants with access to DYD control visited the site less often (mean 1.24, SD 0.75) and downloaded fewer pages (mean 13, SD 12). As mentioned in Chapter 1, the reach of Internet-based interventions may be high, but access or use is often low (Christensen et al. 2006; Cunningham et al. 2009; Eysenbach 2005). If participants are not using the intervention as intended they may not be receiving the components necessary for behaviour change. However, these 'active ingredients' of effective brief interventions remain undetermined, with this a key direction for future research (Kaner 2010). There was no prescribed use of DYD intervention as participants may have been at different stages with their drinking, e.g. if already motivated to reduce their drinking then much of phase 1 is not applicable. Qualitative interviews with DYD participants found that people were indeed using different parts of the website according to their needs (see Chapter 6).

## **Primary and secondary outcomes**

There was no significant difference between experimental groups for any of the drinking outcomes at any of the time points assessed. A reduction in alcohol consumption was, however, found across both groups in all outcomes, including a reduction of 20 units per week at 3 months to almost within safe drinking limits (see Table 4 DYD trial results) (see Chapter 1 for safe drinking limits).

**Table 4. DYD trial results – drinking outcomes**

Alcohol consumption per week	Time point	Geometric mean (SD)		Adjusted ratio (intervention / control) of geometric means (95%CI) <sup>\$</sup>
		Intervention	Control	
<b>No. of units</b>	0m: n=7,935	46.3 (31.8)	45.7 (30.6)	-
	1m: n=2,067	27.1 (23.1)	27.1 (22.5)	0.98 (0.90 to 1.07)
	3m: n=3,529	26.4 (23.0)	25.6 (21.5)	1.03 (0.97 to 1.10)
	12m: n=854	22.0 (20.0)	23.5 (21.0)	0.99 (0.85 to 1.15)
<b>Max units consumed on any 1 day</b>	0m: n=7,935	15.8 (9)	15.7 (10)	-
	1m: n=2,067	11.3 (9)	11.4 (8)	0.99 (0.93 to 1.05)
	3m: n=3,529	11.1 (7)	10.8 (9)	1.04 (0.99 to 1.09)
	12m: n=854	9.7 (7)	10.1 (7)	0.99 (0.89 to 1.10)
		Arithmetic mean (SD)		Adjusted difference (intervention / control) of arithmetic means (95%CI) <sup>\$</sup>
<b>No. of drinking days</b>	0m: n=7,935	5.0 (2)	5.0 (2)	-
	1m: n=2,067	4.2 (2)	4.2 (2)	-0.13 (-0.28 to 0.02)
	3m: n=3,529	4.1 (2)	4.1 (2)	0.02 (-0.10 to 0.15)
	12m: n=854	3.9 (2)	4.0 (2)	-0.07 (-0.32 to 0.19)
<b>No. of days above recommended limits (&gt;2 ♀ / &gt; 3+ ♂ units of alcohol a day)</b>	0m: n=7,935	4.8 (2)	4.8 (2)	-
	1m: n=2,067	3.9 (2)	3.9 (2)	-0.10 (0.25 to 0.06)
	3m: n=3,529	3.8 (2)	3.8 (2)	0.01 (-0.12 to 0.13)
	12m: n=854	3.6 (2)	3.7 (2)	0.03 (-0.23 to 0.29)
<b>No. of days binge drinking (&gt;6 ♀ / 8+ ♂ units of alcohol)</b>	0m: n=7,935	3.6 (2)	3.5 (2)	-
	1m: n=2,067	2.5 (2)	2.5 (2)	-0.03 (-0.18 to 0.12)
	3m: n=3,529	2.3 (2)	2.4 (2)	-0.07 (-0.18 to 0.05)
	12m: n=854	2.1 (2)	2.2 (2)	0.00 (-0.22 to 0.22)

\$Adjusted for baseline alcohol consumption, AUDIT-C, age, sex, education, self-efficacy and EQ5D; m: month.

Self-efficacy scores improved over time, but with no difference between experimental groups (except at 1 month where they were significantly higher in the intervention group). Intention scores decreased slightly, again in both groups, at all follow-up assessments. There was no significant difference in EQ-5D scores between experimental groups and no change over time. There was also no significant difference between arms for any of the secondary outcomes, but an improvement was found in both groups over time (except on the LDQ at 3 months).



## ***Interpretation of findings***

The DYD research team offered several possible explanations for the findings of this trial. One explanation was that both intervention and control areas of the website were equally effective at reducing alcohol intake. Another was that neither experimental arm was effective and that the reduction in drinking was due to regression toward the mean and/or reactivity of assessment. Regression toward the mean is a statistical phenomenon whereby a sample of people selected for their high scores (or high level of need) will score lower on a repeated measurement (i.e. appear to improve) as the score regresses toward the average for the population (Morton & Torgerson 2003). It is possible that DYD participants identified the site and self-recruited to the trial at a point in which their drinking was a particular concern, and that they would have reduced their drinking by chance, over time, regardless of the website. It is also possible that the trial assessment measures may have influenced people's drinking behaviour. Assessment measures used to determine alcohol consumption are known to be reactive, i.e. lead to a reduction in drinking (Carey et al. 2006; Kypri et al. 2007; McCambridge 2009; McCambridge & Day 2008). This phenomenon was explored further in Chapters 4 and 6. Qualitative research with participants in the UKATT trial (a multi-centre trial comparing motivational enhancement therapy with social behaviour and network therapy for alcohol problems) found trial assessment measures to motivate behaviour change (Orford et al. 2006a). Qualitative interviews with DYD participants echo this finding and suggest an additional impact of screening and follow-up prompts (see Chapter 6).

People frequently change their drinking behaviour without treatment (Cunningham 1999; Saunders & Kershaw 1979; Sobell et al. 1991; Sobell et al. 1996). The context in which participants self-recruited to the DYD trial, i.e. searching for help or information on their drinking, suggested some motivation to address their behaviour. The Internet provided a gateway to resources both on- and offline. Through searching the Internet for help to

reduce their drinking, people are likely to encounter a range of services that they may or may not utilise. In a motivated participant group, this could mean that people are accessing a number of different resources until they find something that is of help to them. Qualitative interviews with DYD trial participants helped illuminate the results of the trial by exploring people's experience of searching for help online, using an Internet-based intervention and taking part in an online trial (see Chapter 6).

The DYD RCT was conducted in adult hazardous drinkers from the general population and would have been eligible for inclusion in the systematic review (Chapter 2). Unlike other studies of adults from the general population (Hester et al. 2005; Hester & Delaney 1997; Riper et al. 2008b), the DYD trial did not find a difference between the intervention and minimally active comparator group in alcohol consumed per week. However, despite its large sample size, including the DYD trial results in the meta-analyses would not have changed the overall finding that computer-based interventions were more effective than minimally active comparators. Nevertheless, inclusion of the DYD trial in a post-hoc sensitivity analysis of those studies in non-students that used suitable measures of central tendency (Hester et al. 2005; Neumann et al. 2006; Wallace et al. 2011) would have resulted in no difference between groups, as observed with studies in student samples. The DYD RCT was not the only trial of a computer-based intervention for reducing alcohol intake to have been published since the completion of this review, and therefore the overall impact of these data is unknown.

An important consideration for future reviews in this field is the extent to which trials assess the efficacy or effectiveness of a computer-based intervention. Much of the research on brief interventions delivered both online and in-person lacks generalisability to the population of interest (Cunningham & Van Mierlo 2009; Kypri 2007; Kypri & Cunningham 2008). Conducting the DYD trial over the Internet provided greater

generalisability to its target population. The following chapter reports on the development and validation of an online measure of past-week alcohol intake, which allowed for the evaluation of the DYD intervention to take place online.

## Chapter 4: Development of an online measure of past-week alcohol consumption – comparability and reliability studies

### ***Chapter overview***

Valid measures of alcohol consumption are needed to evaluate the effectiveness of Internet-based alcohol misuse interventions over the Internet. A methodological challenge of transferring alcohol consumption measures to the online setting is that they may not retain their psychometric properties. Few studies have investigated the comparability of conventional measures (i.e. paper-based questionnaires or in-person interviews) with their online equivalents, which is vital for strengthening the methodological rigour of online trials in this field. The Down Your Drink trial needed a valid online measure of alcohol intake to assess its primary outcome of past-week drinking. The aim of this chapter is to report on the development of the TOT-AL (total past-week alcohol consumption), its test-retest reliability, and comparability with the in-person approach to eliciting alcohol intake. These studies assessed 1) the ability of the TOT-AL to produce consistent results (reliability), and 2) the extent to which the TOT-AL produced comparable results with the in-person approach, on which it was modelled. The TOT-AL represents one of the first online measures of alcohol intake available for use by other researchers. It provides a time-efficient means of collecting self-report data in any setting with Internet access and has the capacity to calculate a range of commonly measured drinking outcomes that reflect different patterns of alcohol intake.

## ***Background***

A problem that faces all researchers evaluating alcohol misuse interventions is choosing a suitable outcome to determine its effectiveness. As mentioned in Chapter 2, alcohol intake represents a proximal measure of harm and is particularly appropriate in studies of hazardous drinkers who are at increased risk, but yet to experience, alcohol-related harm. Self-report is the most widely used means of eliciting drinking behaviour in research with hazardous and harmful drinkers, providing a valid, reliable and feasible approach when compared with biochemical markers, coverage of sales data and collateral reports (Connors & Maisto 2003; Del Boca & Darkes 2003; Midanik 1988; Rehm 1998). As discussed in Chapter 2, self-reported alcohol consumption can be assessed using a number of different measures, in different formats, to produce a variety of drinking outcomes. There is no obvious 'front runner' or 'gold-standard' approach used in this field as different drinking outcomes represent different patterns of drinking. Alcohol can be reported as actual or average consumption and recalled retrospectively or prospectively over periods of one day to twelve months. The choice of self-report measure should be based on the objectives of the research and the purpose of the intervention, consideration of sample characteristics, the setting of the research and the resources available (Allen 2003; Del Boca & Darkes 2003; Stout 2003). Commonly reported outcomes in similar studies should also be considered so that the impact of these interventions can be meaningfully compared.

The DYD trial needed a measure of alcohol consumption that detected differences between experimental groups and change in consumption over time. A measure of actual consumption was selected by the DYD research team, which required retrospective recall of past-week drinking. Weekly drinking requires recall of every alcoholic beverage consumed on each of the previous seven days, starting with the most recent (Rehm 1998). The justification for choosing this measure is outlined below:

- Actual recall: To provide as accurate recall as possible. Also allows for calculation of secondary measures;
- Retrospective recall: Less onerous and reactive than prospective recall;
- One week recall period: Trade-off between accuracy of recall and typicality of drinking behaviour;
- Beverage-specific: Easier to recall actual beverage-specific consumption than estimation of standard drinks.

The DYD trial was conducted over the Internet in its entirety and therefore necessitated a web-based measure of past-week alcohol intake. Self-reported alcohol consumption has been ascertained via a range of modalities, including in-person and telephone interviews, voice-recognition software, paper-based and computer-based questionnaires. Web-based measures of alcohol consumption have become increasingly popular due to the numerous advantages of this approach (Cunningham et al. 2005; Cunningham et al. 2006a; Koski-Jannes et al. 2007; Kypri et al. 2004b; Kypri et al. 2004a; Kypri & McAnally 2005; McCabe et al. 2006a; McCabe et al. 2006b; Miller et al. 2002; Riper et al. 2008b; Saitz et al. 2007). Computerised screening and assessment was used in many of the studies included in the systematic review (Chapter 2), where responses were used to generate personalised feedback – a common feature of the interventions. Online data collection is instantaneous; this saves the researcher time and eliminates the likelihood of error caused by manual data entry. Online measures are potentially easy to use and can be tailored to individual responses, thus minimising the amount of irrelevant information that is presented. Computerised measures of alcohol consumption have been found to be acceptable to participants in several studies (Bendtsen & Timpka 1999; Bernadt et al. 1989; Skinner & Allen 1983), with many participants preferring them to more conventional measures (Miller et al. 2002). They provide anonymity, which some studies have suggested may improve

veracity when reporting sensitive behaviours (Duffy & Waterton 1984; Gerbert et al. 1999; Turner et al. 1998); this was also the experience of the DYD trial (see Chapter 6). Response rates have been found to be higher in some web-based surveys compared with their paper-based counterparts (McCabe et al. 2006a; McCabe et al. 2002; Ritter et al. 2004), thus reducing the possibility of non-response bias (discussed in Chapter 5). The costs associated with data collection are also thought to be minimal compared with mail, telephone or in-person alternatives, allowing for recruitment of larger sample sizes with relative ease.

An important methodological concern when transferring a measure online is that it cannot be assumed to retain its psychometric properties (e.g. its reliability and validity) (Buchanan 2002; Miller et al. 2002; Ritter et al. 2004; Wantland et al. 2004). The reliability of a measure is the extent to which it provides consistent results, while its validity is the degree to which it measures what it was intended to measure. The use of reliable and valid measures is needed to strengthen the methodological rigour of online research. Studies have demonstrated the comparability of various paper-based measures of alcohol intake and alcohol-related problems with their web-based counterparts (Kypri et al. 2004a; McCabe et al. 2006a; McCabe et al. 2006b; McCabe et al. 2002; Miller et al. 2002). These studies compared validated screening tools for at-risk drinkers (i.e. AUDIT), measures of alcohol dependence (i.e. Alcohol Dependence Scale - ADS) and measures of alcohol-related problems (i.e. Rutgers Alcohol Problem Index - RAPI). Alcohol intake ascertained in an in-person interview was also found to produce comparable results with its computerised equivalent (Bernadt et al. 1989; Duffy & Waterton 1984; Skinner & Allen 1983). However, these comparisons are not commonplace, and the issue of transferability is rarely considered. Also lacking from the literature were investigations of test-retest reliability or other psychometric properties to accompany online measures of alcohol

consumption. Reliability is vital as a measure cannot be valid unless it is reliable (Miller et al. 2002; Rehm 1998; Thomas & McCambridge 2008).

Another important consideration when measuring alcohol consumption is its impact on behaviour. Reactivity of assessment (also known as the Hawthorne effect) is the phenomenon whereby the process of assessment acts as a catalyst to behaviour change. The impact of assessment on alcohol consumption has been demonstrated in a number of studies (Carey et al. 2006; Kypri et al. 2007; McCambridge 2009; McCambridge & Day 2008), and has been observed in other behaviours (French & Sutton 2010). Reactivity of assessment was offered as one explanation for the reduction in alcohol consumption across both groups of the DYD trial (see Chapter 3). This explanation was supported to some extent in qualitative interviews with DYD participants, where assessment measures reportedly helped participants to determine the severity of their problem and to prompt a change in their drinking (see Chapter 6). There is no consensus as to why a reduction in alcohol intake occurs after assessment. One explanation is that it raises awareness of risky drinking, hence resulting in problem recognition. This discrepancy between perceived drinking and actual drinking may then lead to a change in behaviour (Carey et al. 2006). Another explanation for assessment reactivity is 'social desirability bias' (CROWNE & MARLOWE 1960), where participants "under-report socially stigmatized behaviours or over-report socially desirable ones." p.68 (Kypri et al. 2007). The impact of social desirability on the accuracy of reporting might, however, be mediated by the format of the measure, where the online setting is thought to increase the perception of confidentiality and therefore result in greater veracity (Crutzen & Goritz 2010; Del Boca & Darkes 2003; Richman et al. 1999). Although reactivity of assessment may be hard to avoid, certain measures of alcohol intake may increase its likelihood, such as prospective recall where alcohol consumption is reported on a daily basis.



There was no freely available web-based measure of past-week drinking at the time the DYD trial protocol was developed, thus necessitating development of a measure for use in the DYD RCT. The DYD team required a tool that was modelled on the in-person approach to eliciting past-week alcohol intake in primary care. The measure required recall of retrospective, beverage-specific alcohol intake over the past week. It was designed for use as a research tool for the anonymous reporting of past-week alcohol consumption in a population with access to the Internet. The TOT-AL<sup>®</sup> (TOTal past-week ALcohol consumption) (Khadjesari et al. 2009) consisted of a series of webpages that instructed the user to enter their alcohol intake via drop-down menus. A step-by step guide to using the TOT-AL is described below:

Step 1: The user was provided with a username and password, allowing for comparison of data at different time points.

Step 2: After logging onto the TOT-AL, the user was presented with a welcome page that provided instructions on how to use the tool (see Figure 9).

**Figure 9. TOT-AL welcome page**

## Total Past Week Alcohol Consumption Calculator

Welcome, **Username**

We would like you to tell us how much alcohol you have consumed over the past week, starting with yesterday. We have provided you with some *Tips to Remember* to help you with this task.

Please start by choosing the type of drink you had from the drop down menu.

Then select the brand of the drink. Don't worry if your brand isn't on the list, or if you can't remember/don't know the brand, just choose "Other".

We'd then like to know the size of the drink. If the size you want does not appear on the list, pick the nearest size.

And finally we'd like to know how many of this type, brand and size you consumed on this day.

**Click here to start »**

Step 3: The next page presented yesterday's date and asked the user, "Did you drink any alcohol on this day?" If they clicked "yes", a series of questions with corresponding drop-down menus appeared. The user was asked to select the type (e.g. beer), brand (e.g. Corona), volume (or vessel, such as bottle) and quantity of this drink, where each of the subsequent drop-down menus reconfigured according to the type of drink selected (see Figure 10).

**Figure 10. TOT-AL drinks entry page**

On this day I drank

Which brand?

Which volume?

How many?

### Can't find your drink listed?

Type the name of the drink or brand of drink in the search box below, and then click 'Search'.

If you drink cocktails, please hazard a guess at how many shots of spirits or other type of alcohol you think it may have contained.

### Tips that may help you remember

The following points might help you to remember how much you drank on any given day. Ask yourself these questions:

- Where were you that day? (e.g. work, college, home, holiday, etc)
- It may help to separate the day into morning, afternoon and evening (ie. morning and afternoon at work, evening in the pub)
- Who were you with? (e.g. colleagues, friends, family, etc)
- What were you doing? (i.e. watching TV, at a sports club or dance lesson, etc)

Step 4: Once this information was entered, the user was asked if they consumed any more alcohol on that day. If they clicked “yes”, they repeated the process again, if they selected “no” they were presented with the date of the day before yesterday and asked if they had consumed any alcohol on that day. The procedure was repeated for each of the last seven days.

Step 5: If users found it difficult to recall the drinks they consumed, the TOT-AL provided “Tips to remember”, these were listed on the right-hand side of the screen and asked participants to think about where they had been that day, who they had been with, and what they were doing (see Figure 10).

Step 6: The drinks entry page provided a search facility for users who were unsure what type of alcohol they had consumed. For example, a search for ‘Martini’, suggested that it may come under the category of alcopop, fortified wine or wine (see Figure 10).

Step 7: Once the task was complete, participants were presented with a table of their weekly intake and asked if they would like to view or amend the information (see Figure 11), before being thanked for their time. The TOT-AL did not provide the participant with feedback on their consumption; this was to limit the effect of the assessment on drinking behaviour.

**Figure 11. TOT-AL weekly summary**

Summary: Week Tuesday 15th July to Monday 21st July		
Monday, 21st July	Various drinks	<a href="#">view / amend</a>
Sunday, 20th July	No drinks on this day	<a href="#">view / amend</a>
Saturday, 19th July	Bombay Sapphire, Large single (35ml) 1	<a href="#">view / amend</a>
Friday, 18th July	Various drinks	<a href="#">view / amend</a>
Thursday, 17th July	Various drinks	<a href="#">view / amend</a>
Wednesday, 16th July	No drinks on this day	<a href="#">view / amend</a>
Tuesday, 15th July	No drinks on this day	<a href="#">view / amend</a>

Once you have reviewed the summary above and are happy with the information you have provided, **[please click here »](#)**

The TOT-AL converted this information into units of alcohol (where one unit approximates to 8 grams of alcohol). Units were calculated by an underlying computer programme accessing a large database of over 4000 alcohol brands with their corresponding %ABV (percentage of Alcohol by Volume – the amount of ethanol contained within a drink) (The Big List 2006) and applying the following formula:

$$\text{Alcohol unit} = (\%ABV \times \text{ml}) / 1000$$

The alcohol brands included in the drop-down menu represented the top 20%, by value, of all brands sold in supermarkets and convenience stores in the UK in 2006 (TNS Worldpanel 2006).

Once the TOT-AL had been created it was tested for its reliability and comparability with the in-person approach to eliciting alcohol intake, before being used as the primary outcome measure in the DYD RCT. The remainder of this chapter reports on the conduct of these studies.

### ***Aims and objectives***

The aim of these studies was to determine the test-retest reliability of the TOT-AL, and to compare it with the in-person approach of eliciting past-week alcohol consumption in a population with access to the Internet. Specific objectives were:

- To determine the degree to which repeated measures of the TOT-AL agreed with each other;
- To determine the extent to which the TOT-AL agreed with the in-person approach to obtaining past-week drinking;

- To determine the impact of gender on the comparability and repeatability of measures;
- To investigate a potential order effect in the comparability study.

## ***Methods***

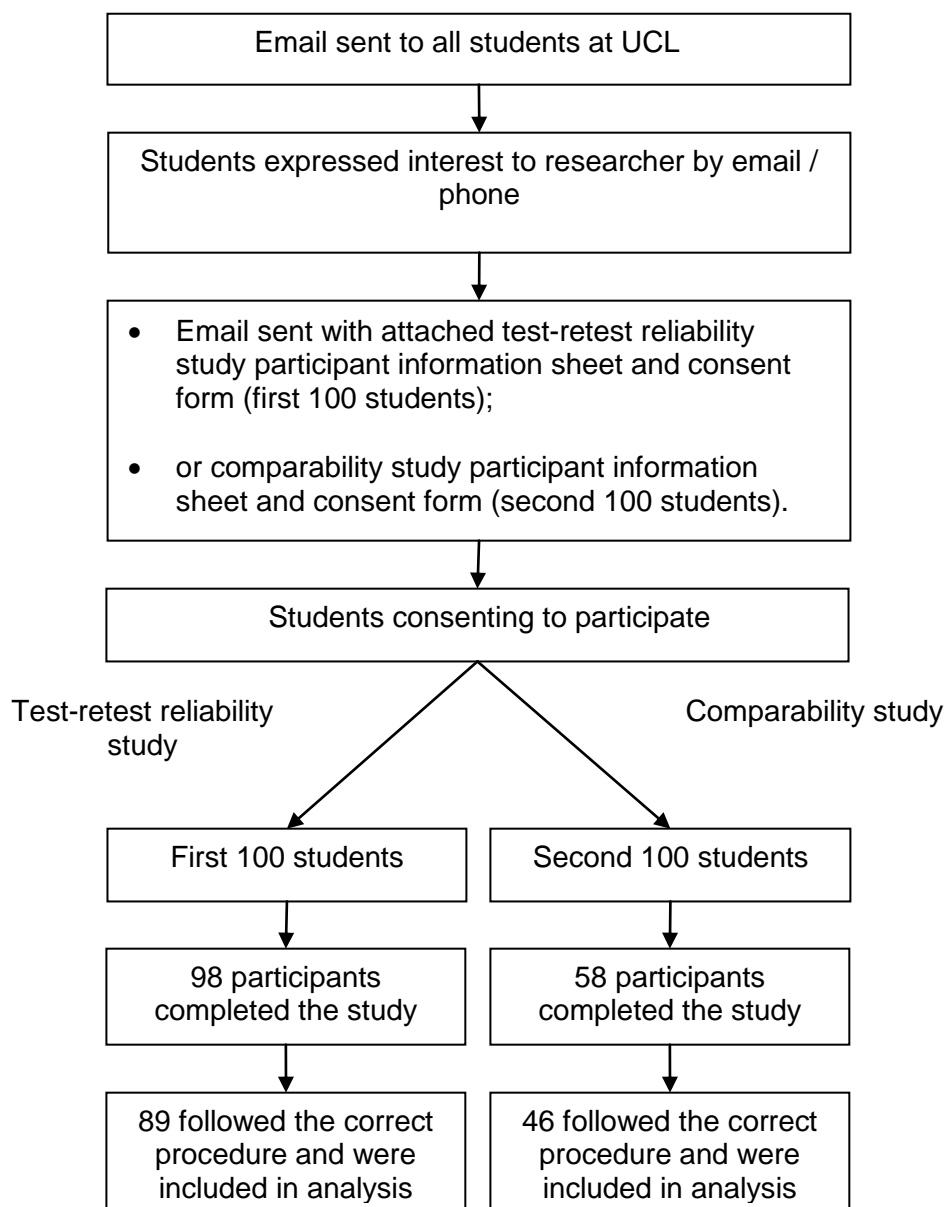
Ethical approval was granted from University College London (UCL) Research Ethics Committee. The test–retest reliability study and the comparability study were conducted in parallel with different study samples (see Figure 12).

### **Sample size**

The DYD statisticians (IW and EK – see Acknowledgements) calculated, *a priori*, that an estimated sample of 100 participants in each study would provide 89% power to demonstrate that the correlation was larger than 0.65, and 77% power to demonstrate that the mean difference between the two methods was smaller than plus or minus 10%; both at the 5% significance level. A maximum difference of 10% was determined for the Bland-Altman analysis, in accordance with standard practice (Bland & Altman 1999) (see below for details on this method).



**Figure 12. Flow chart of study procedure**



## **Participants**

Eligible participants were University College London students. The university setting was ideal for the conduct of these studies as hazardous drinking is highly prevalent among students (see Chapter 2) (Bewick et al. 2008a; Gill 2002), and access to the Internet is universal. Students also provide a large pool of easily accessible participants who are generally willing to participate in research. Eligible participants were aged 18 years and

above and drank alcohol (i.e. not teetotal), as this would prevent comparison between the measures.

Participants were recruited for both study samples by emailing undergraduate and postgraduate students. The first 100 students who responded were sent a participant information sheet and consent form (as Microsoft Word attachments to an email) for the test–retest reliability study, whilst the second 100 volunteers were sent documents for the comparability study. A cash incentive of £10 was offered for participation in the study, payable on completion of both measures.

### **Procedure**

On receipt of a signed consent form, participants in the test–retest reliability study were sent (via email) a unique username, password and hyperlink to the TOT-AL. They were instructed to complete the TOT-AL twice on the same day, but with a minimum of 3 hours apart (the start and finish times and date of the two TOT-AL completions were recorded automatically by the TOT-AL). Both completions needed to reflect the same seven-day period and the gap in time was designed to minimise the likelihood of recall of previous answers. Participants in this study had the flexibility of choosing any convenient day, time and location to complete the TOT-AL.

Participants in the comparability study were asked to book a convenient time for a brief face-to-face interview on receipt of their consent form. The order in which participants completed the interview and the TOT-AL was randomly assigned to them using a computer-generated random number table (OO'D – see Acknowledgements). This was to control for possible effects of learning and recall related to either method of data collection. Interviewers (ZK and CGH – see Acknowledgements) were blinded to the order of the

measures. Participants were sent a confirmation email (OO'D) with the date and time of their interview and reminding them to complete the TOT-AL on the same day, but at least 3 hours apart. The email also contained a hyperlink to the TOT-AL and their unique username and password. All interviews were conducted at the University of London Union, a central location freely accessible to all participants.

The interviewers (ZK and CGH) attended a two-hour training and practise session in recording alcohol consumption, led by a General Practitioner (EM). The interviews began by confirming the interviewee's identity, explaining the procedure, recording their age, gender, and the time the interview commenced and subsequently ended. Participants were reassured that the information they provided would be kept confidential and that the data they provided would be anonymised. Participants were then asked to recall what alcohol they had consumed over the past week, starting with yesterday. They were asked to do this by reporting the type, brand, volume and quantity of the alcohol they consumed. If participants found it difficult to remember what they had drunk, prompts were provided (e.g. Can you remember what you were doing on that day? Can you remember where you might have been and whom you might have been with?). These prompts were also visible when completing the TOT-AL (see Figure 10). The interviewers recorded responses on a pre-designed, paper-based calendar that provided separate sections for each of the last seven days.

### **Data analysis**

For the test–retest reliability study, the data were transferred from the Excel spreadsheet used by the TOT-AL into an SPSS database. For the comparability study, data from the interviews were calculated into units independently, in duplicate (ZK and DYD statistician (EK)), using The Big List of alcohol brands (The Big List 2006) to find the %ABV.

Duplicate calculation of units from the interviews was performed to reduce interviewer bias, and so that the differences between the TOT-AL and the interview were not a result of miscalculated units. There was a high level of agreement in calculation; discrepancies tended to occur when calculating the units in cocktails when the content of alcohol was not specified by the participant. This was resolved by deciding on a standard two units per cocktail. The units were entered into an SPSS database, along with the participant's unique identifier, date of interview, start and finish times, gender and age. The data from the TOT-AL were transferred from the Excel spreadsheet into the SPSS database.

A similar statistical approach was used to analyse the data in both the test–retest reliability study and the comparability study. Descriptive statistics were used to summarise the sample characteristics (see Table 5), scatter plots were constructed to show the relationship between the measures (see Figures 13 and 15), and the differences between the two measures were calculated (Table 6). The correlation between the measures was assessed using Pearson's Correlation Coefficient, with Fisher's Z transformation used to calculate a 95% confidence interval. The correlation between the measures was also analysed separately by gender. To investigate the presence of an order effect in the comparability study, the correlation between the measures was analysed separately for each order of completion.

The correlation between the measures was calculated, as this is the conventional approach to comparing methods (or repeated measurements) and therefore allows for easy interpretation by other researchers. However, the correlation coefficient approximates the strength of the relationship (association) rather than the agreement between the two measures. A high association does not necessarily result in good agreement and a change in measurement scale would not affect the correlation between the measures; however, it would affect the agreement (Bland & Altman 1986).

A Bland-Altman analysis was chosen as the most suitable analytical approach for assessing the level of agreement between 1) repeated measurements of the TOT-AL and 2) the TOT-AL and the in-person interview. This approach is used when a new measure is compared with an existing, established measure, but where the true values remain unobtainable due to the absence of an objective measure. The analysis determines the extent to which the measures differ, and whether they can be used interchangeably. The Bland-Altman analysis plots the difference between the measures against the mean (known as the bias) for each participant (Bland & Altman 1986). This is estimated by the mean difference and the standard deviation of the differences. The plot illustrates whether “the variability of differences between methods is roughly constant across the range of measurement” p. 801 (Altman & Bland 2002). The 95% limits of agreement (or 95% range of differences) are calculated as the mean difference between the measures plus or minus 1.96 times its standard deviation. The limits of agreement provide an upper and lower limit within which 95% of differences between the two methods should lie.

Alcohol consumption was log-transformed because the raw data showed a strong ‘funnel-shaped’ relationship between mean and difference. In other words, the variability of differences was not constant across the range of measurement. When the variability (or scatter) of differences increases as the measurement increases, log transformation of the observed data is advised. Analysing the data in its raw state would result in agreement limits that were either wider apart than necessary for low units or narrower than they should be for higher units. The data were therefore log-transformed before producing the final Bland-Altman plot, and the anti-logs of the limits were interpreted as a percentage difference between measures above and below the mean.

For the test-retest reliability study, the estimated standard deviation of the differences was calculated. This was achieved by adding together the squared differences divided by the

total and taking the squared root (Bland & Altman 1986). The limits of agreement were calculated as the mean difference between the measures plus or minus 1.96 times its standard deviation. For the comparability study, a difference (between the measures) of up to 10% was determined, before data collection, in accordance with standard practice. Should the mean differences lie within the upper and lower limits then the two measures are deemed interchangeable, or the new measure can replace the existing measure. These analyses were undertaken by the DYD statisticians (IW and EK).

## ***Results***

One hundred participants initially consented to take part in the test–retest reliability study. Two participants failed to take part, eight participants only completed the TOT-AL on one occasion or completed it for the second time on a different day, and three participants did not report consuming any alcohol in the past week and were therefore excluded from the analyses (as not possible to log transform zero). A total of 87 participants were included, consisting of 52 (60%) women and 35 (40%) men. The average age was 24 years, with ages ranging from 18 to 44 years. When the TOT-AL was completed for the first time it took participants an average of four minutes and 43 seconds to complete, dropping to three minutes and 11 seconds on the second completion. Average reported weekly alcohol consumption was 22.2 units per week according to the TOT-AL on first completion (women 18.9 units per week, men 27.2 units per week) (see Table 5). The mean length of retest period was five hours and 10 minutes, which ranged from two hours and 57 minutes, to 11 hours and 42 minutes. Two participants completed the TOT-AL for a second time slightly less than 3 hours later (2 hours 57 minutes and 2 hours 58 minutes).

One hundred participants consented to take part in the comparability study. Of these, 54 did not complete the study: 42 participants did not arrange an interview or failed to attend

their interview, and 12 participants did not follow the study procedure correctly, either by not completing both measures on the same day or by only completing one of the measures. Thus, 46 participants were included in the comparability study (28 women (61%) and 18 men (39%)). The participants in this study sample were between the ages of 18 and 53 years, with an average age of 24 years. The average length of time taken to complete the interview was three minutes and 28 seconds, while the average time taken to complete the TOT-AL was four minutes and 17 seconds. The mean number of units consumed by participants (according to the interview) was 21.6 units of alcohol per week (women 17.1 units/week; men 28.5 units/week) (see Table 5). The average retest period was five hours and 15 minutes, ranging from one hour and 49 minutes, to 13 hours and 46 minutes. Four participants completed the second measure less than 3 hours later (1 hour 49 minutes, 2 hours 38 minutes, 2 hours 51 minutes and 2 hours 56 minutes).

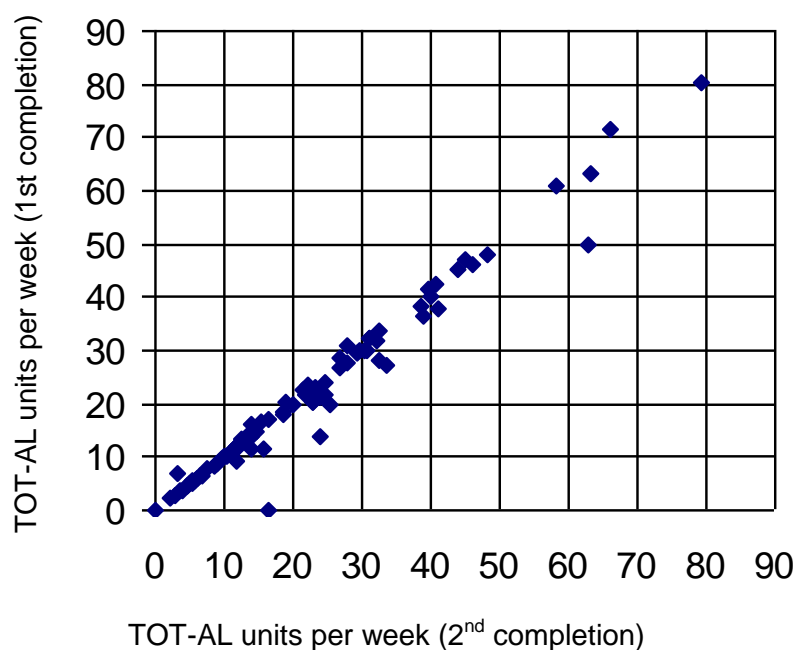
**Table 5. Participant characteristics, time taken for completion of measure and past-week alcohol consumption (units of alcohol)**

	Gender (no. of participants)		Age (yrs)		Duration of completion (mins)		Weekly consumption (units of alcohol)		
	Male	Female	Mean (SD)	Range		Mean (SD)		Mean (SD)	Range
<b>Test-retest reliability study</b>	35	52	24 (4.03)	18-44	TOT-AL 1	4:43 (2:48)	TOT-AL 1 (Male)	22.23 (16.14)	2.13 – 79.16
							(Female)	27.22 (19.62)	3.86 – 79.16
								18.88 (12.42)	2.13 – 66.21
					TOT-AL 2	3:11 (3:27)	TOT-AL 2 (Male)	21.86 (16.14)	2.13 – 80.09
<b>Comparability study</b>	18	28	24 (6.7)	18-53			(Female)	26.83 (19.47)	3.86 – 80.09
					Interview	3:28 (1:39)	Interview (Male)	18.51 (12.57)	2.13 – 71.33
							(Female)	21.58 (15.09)	1.41 – 62.34
								28.50 (15.53)	7.56 – 62.34
					TOT-AL	4:17 (3:21)	TOT-AL (Male)	17.14 (13.24)	1.41 – 51.94
							(Female)	21.93 (14.23)	1.88 – 52.74
								28.02 (13.90)	7.70 – 52.74
								18.01 (13.24)	1.88 – 49.65

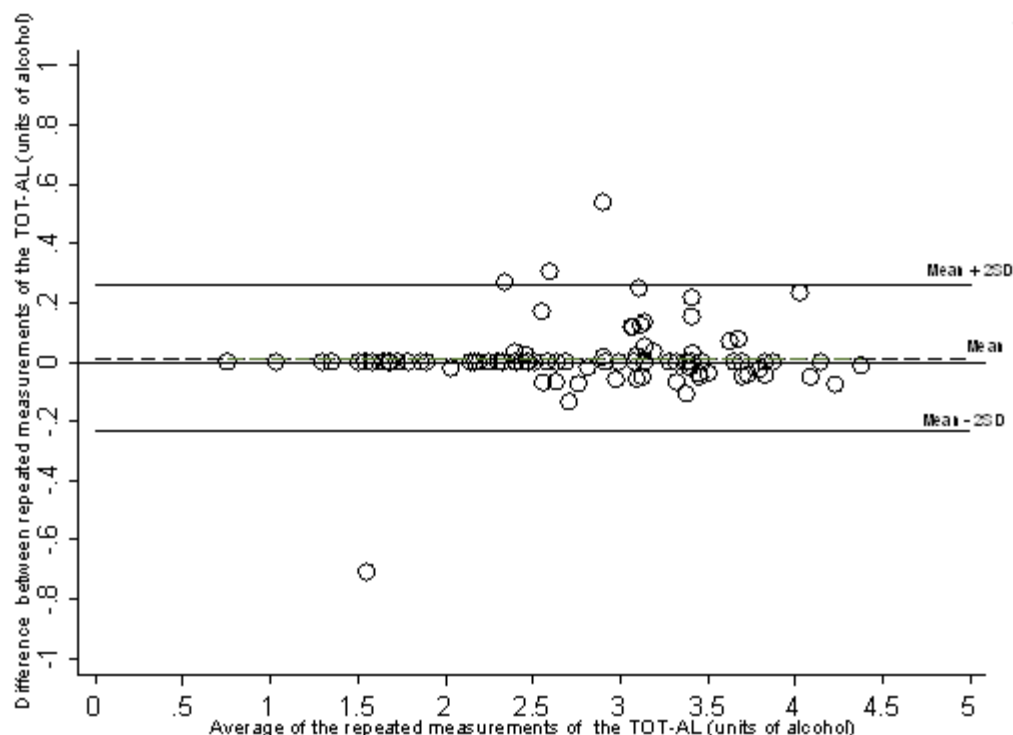


A scatter plot was used to visualise the relationship between the units calculated on both completions of the TOT-AL (see Figure 13). This plot illustrated a very strong correlation between the repeated measurements, with most of the points lying close to the equality line ( $r=0.99$ ; 95% CI: 0.98, 0.99). The Bland–Altman plot was constructed using the log-transformed data (see Figure 14). There was a high level of agreement between the repeated measurements.

**Figure 13. Correlation between units calculated by the TOT-AL on 1st completion and on 2nd completion**



**Figure 14. Bland-Altman plot of agreement between repeated measurements of the TOT-AL (log-transformed data)**



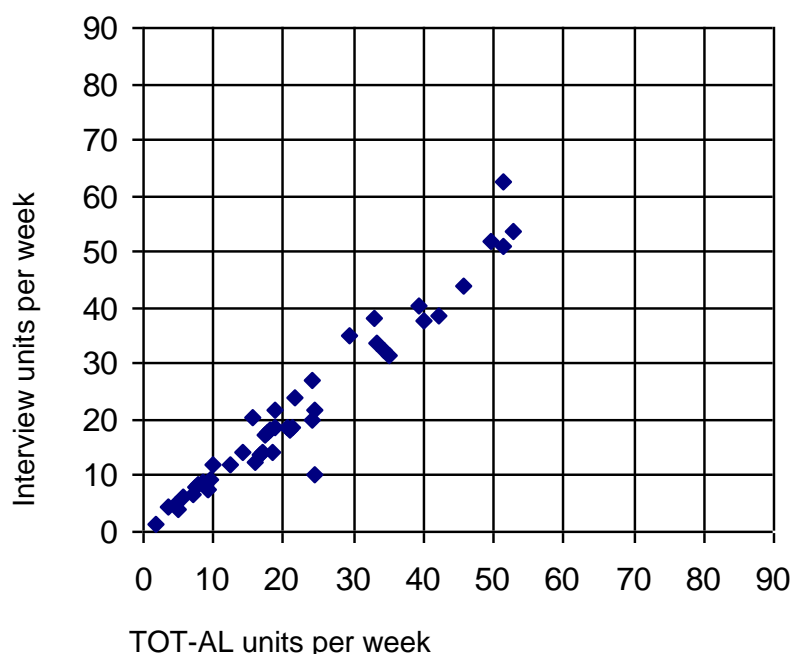
The units calculated by the TOT-AL (first completion) were 1.01 times higher (1.3% higher) than those calculated on the second completion of the TOT-AL, where for 95% of the differences the second TOT-AL score was between 0.80 times below (20% below) and 1.30 times above (30% above) the first TOT-AL score (see Table 6). The agreement between the measures was analysed separately for men and women. Both genders appeared to generate a similar level of agreement (see Table 6).

**Table 6. Agreement and correlation between repeated measurements of the TOT-AL and between the TOT-AL and the interview**

	Number of participants	% difference (95% CI)	Limits of agreement	Correlation (95% CI)
<b>Test-retest reliability study</b>				
Overall	87	1.3 (-1.3, 4)	20% below 30% above	0.99 (0.98, 0.99)
Men	35	1.5 (-2.2, 5.2)	20% below 26% above	0.99 (0.99, 1)
Women	52	1.2 (-2.5, 5)	22% below 31% above	0.98 (0.97, 0.99)
<b>Comparability study</b>				
Overall	46	4 (-1.7, 9.3)	27% below 50% above	0.97 (0.95, 0.99)
Men	18	0.5 (-6, 7)	23% below 30% above	0.98 (0.94, 0.99)
Women	28	6 (-2.4, 14)	30% below 61% above	0.97 (0.93, 0.98)
TOT-AL first	25	-1.5 (-6, 3)	19% below 20% above	0.99 (0.98, 1)
Interview first	21	10.6 (-0.7, 21)	32% below 80% above	0.96 (0.90, 0.98)

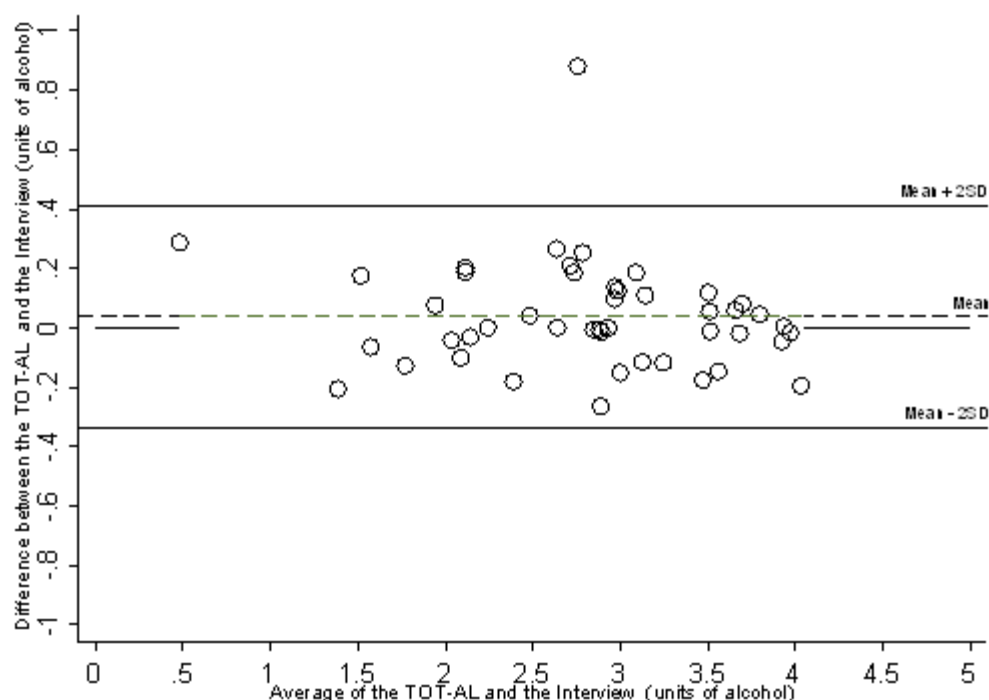
The relationship between the units calculated by the TOT-AL and the interview were displayed in a scatter plot (see Figure 15). The plot demonstrated the high correlation between the units calculated by the TOT-AL and the face-to face interview ( $r = 0.97$ ; 95% CI: 0.95, 0.99).

**Figure 15. Correlation between units calculated by the face-to-face interview and the TOT-AL**



The Bland–Altman plot of the log-transformed data showed no evidence of systematic bias (see Figure 16). There was a high level of agreement between the measures; units calculated by the TOT-AL were 1.04 times higher (4% higher) than the interview, where for 95% of the differences the interview score was between 0.73 times below (27% below) and 1.50 times above (50% above) the TOT-AL score (see Table 6). The mean difference (or average bias) between the two methods was 4% (95% CI: –1.7, 9.3), which was less than the 10% specified *a priori*. The mean of the differences and the associated confidence interval was very small but the agreement limits were wide, thus indicating that while most participants had scores in agreement, there were few whose measurements were quite different – mainly the heavier drinkers.

**Figure 16. Bland-Altman plot of agreement between the TOT-AL and the face-to-face interview (log-transformed data)**



In general, there was good agreement between measures for both genders (see Table 6). The difference between the interview and the TOT-AL was greater when the interview was completed first compared with when the TOT-AL was completed first ( $P=0.03$ ).

## ***Discussion***

The TOT-AL was found to be a reliable measure, comparable to the in-person approach to eliciting past-week alcohol consumption. This finding of comparability between measures delivered by different modalities was consistent with previous studies, where a variety of commonly used paper-based measures of alcohol use were compared with their web-based equivalent in student samples (Kypri et al. 2004a; McCabe et al. 2006a; McCabe et al. 2006b; McCabe et al. 2002; Miller et al. 2002), and where the in-person interview was compared with its computerised equivalent in non-student samples, i.e. adult males from

the general population (Duffy & Waterton 1984), help-seekers contacting an addiction treatment centre (Skinner & Allen 1983), and general psychiatric admissions (Bernadt et al. 1989). This study was the first, however, to compare an in-person interview with an online measure that did not require participants to access a computer in a specific location.

Interestingly, comparability was not achieved in a previous study of adults from the general population, where participants completing web-based surveys reported higher alcohol consumption than those completing paper-based surveys or telephone interviews (Link & Mokdad 2005). Reporting alcohol consumption online from a remote setting provides privacy and perceived anonymity, which some studies suggest may improve self-reported veracity when reporting sensitive behaviours (Booth-Kewley et al. 2007; Crutzen & Goritz 2010; Duffy & Waterton 1984; Gerbert et al. 1999; Richman et al. 1999; Turner et al. 1998) (see Chapter 6). The perceived repercussions of divulging sensitive information in-person may affect self-reported veracity (Del Boca & Darkes 2003). Preconceptions of an interviewer's professional background have been found to influence responses, where responses differ depending on whether the interviewer introduced themselves as a doctor or a researcher (Richards & Emslie 2000). An interviewer's gender and age have also been found to influence self-reported alcohol consumption, where highest rates of consumption were elicited by male interviewers and where young respondents were questioned by young interviewers (Heeb & Gmel 2001). The privacy of the Internet setting did not improve self-reported veracity in the comparability study reported in this chapter. One explanation might be that the interviewers were students of a similar age to the interviewees. As such, the participants were unlikely to have perceived any repercussions of providing an accurate account of their drinking behaviour. The ability of a computer-based measure to eliminate the bias introduced by interviewer characteristics is a potential advantage of online research and would benefit from further investigation.

A large number of students expressed interest in taking part in the reliability and comparability studies, but only 100 were permitted to complete the consent forms for each study due to the available funds for incentives. The comparability study saw considerable dropout compared with the reliability study. Completion of the TOT-AL took place at a convenient time and location with Internet access, as chosen by the participant, whereas attending an interview required the organisation of a specific time and date, and attendance at a location specified by the researcher. The difference in sample sizes between these studies highlights the convenient nature of a web-based, self-report tool. Despite the small sample size of the comparability study, the confidence intervals were sufficiently narrow to convincingly exclude a clinically important difference between methods in mean reported consumption (see Table 6).

An important observation of both studies was that discrepancies between the TOT-AL and interview scores, and repeated completions of the TOT-AL were greater among heavier drinkers. This may present a problem when the TOT-AL is used in populations of heavier drinkers. It may be that the TOT-AL was an ineffective means of eliciting past-week alcohol consumption, or that the in-person interview was an inconsistent measure. A disadvantage of the comparability study was the lack of reliability data to support the in-person interview. The time and resource constraints of the DYD pilot study prevented the conduct of a reliability study, but this would be a worthy subject for further research. However, the fact that this discrepancy was also evident in the test-retest study challenges the hypothesis that the in-person interview was an inconsistent measure. Several studies have observed the discrepancy between measures among heavier drinkers and suggest that impaired memory due to excessive drinking is likely to be the cause. This discrepancy may also be explained by the fact that heavier drinkers have more drinks to recall, therefore creating a trickier task (Babor et al. 2000). The number of participants classified as heavy drinkers was small, and a larger scale investigation would need to reaffirm the

findings of these studies. Ideally, the participants recruited to these studies would have displayed similar drinking habits to DYD trial participants. The DYD trial had not begun recruiting at the time these studies were conducted and therefore their level and pattern of consumption was unknown. Many students were anticipated to be drinking at hazardous levels (Bewick et al. 2008a; Gill 2002). The average amount of alcohol consumed by participants in both studies was above recommended safe limits, with men consuming around 28 units of alcohol per week, and women consuming around 18 units a week across both studies (see Table 5). However, participants in the DYD trial are now known to have an average baseline consumption of 46 units per week.

An order-effect was observed in the comparability study, where greater agreement between measures was found when the TOT-AL was completed first. This finding is based on a small sample of participants, but is nonetheless worth considering.

Completion of the TOT-AL is an active process; participants are required to read instructions on how to use the measure, using their hands to navigate through the tool and access the dropdown menus, which in turn provide prompts on the type, brand and size of drink. The use of prompts is thought to improve recall, as demonstrated by the timeline follow-back approach to reporting alcohol consumption (Sobell & Sobell 1992).

Participants were found to spend over one minute longer completing the TOT-AL compared with the interview, perhaps suggesting that it provoked greater contemplation of drinking behaviour or that it was a more interesting and novel exercise. The in-person interview required verbal recall, which is a more passive exercise and may access a different type of memory. It seems possible that completing the verbal interview first enhanced the independence of the two tasks. This specific hypothesis is worthy of further investigation. The uncertainty over the nature of this effect emphasises the need for further study of alcohol consumption assessment processes more generally.



An unavoidable limitation of both the test–retest reliability and comparability studies was that they may have been perceived by the participants as memory exercises. A minimum of three hours between completions of the two tasks was required in this study. To avoid over-complicating the analyses, as well as on inferential grounds, it was judged necessary that both measures were completed on the same day so that they would have an identical seven-day reference period. Ideally, replicate observations should be taken independently of each other (Bland & Altman 1986). It was not possible in the design of the reliability study for participants to complete the TOT-AL for the second time independent of the knowledge of completing it the first time. Future research may benefit from an extended retest period, for example, recall of the past eight days with a one day retest period would still allow for a comparison of the seven overlapping days. There are also other ways in which equivalent reference periods may be compared that minimise the potential for recall, and these should be considered in further studies.

The average age of participants in both the comparability and reliability studies was 24 years old. Although the TOT-AL was developed for use in any age group, it must be acknowledged that these findings may not generalise to older people or those with poor computer literacy. Participants in the DYD RCT had universal access to the Internet (determined by the way in which they were recruited), and anonymity was inherent in the nature of an online trial. It is therefore likely that that these results support the use of the TOT-AL in the DYD RCT.

## ***Conclusion***

The TOT-AL was found to be a reliable measure that can be used interchangeably with the in-person approach to eliciting alcohol consumption over the past week. It eliminates human error in the calculation of units and removes the possibility of interviewer

characteristics influencing responses. It can be used on any computer with Internet access as a time efficient means of ascertaining alcohol intake. The TOT-AL was designed for autonomous use, with no supervision or assistance; therefore, these findings may generalise to settings that allow for independent self-completion in remote settings with access to the Internet. The use of a valid measure of alcohol consumption in the DYD RCT improved the methodological rigour of this online trial. The reliability and comparability of measures should be investigated where conventional measures of alcohol intake are applied to the online setting.

### ***Implications for researchers and practitioners***

The TOT-AL is the first readily available web-based measure of beverage-specific, past-week alcohol consumption. It was designed to calculate units of alcohol consumed per week, but also has the capacity to present a range of other commonly used drinking outcomes, such as frequency of drinking days, frequency of binge drinking days, or peak consumption (see Table 4 in Chapter 3). The TOT-AL could potentially be adapted for use in countries outside the UK by modifying the drop-down menus to include the type, brand and size of drinks most commonly consumed in that country. The algorithm could be programmed to calculate grams of alcohol per week rather than units of alcohol, which are country specific.

The TOT-AL was developed as an indicator of effectiveness in a web-based trial (see Chapter 3), yet it could also be used in epidemiological research by simply providing a hyperlink to the website and login details. Researchers looking to reduce cost, ease data collection, reduce the likelihood of bias and increase response rates in certain populations should consider online measures as a viable alternative to conventional modalities.

The TOT-AL may also provide a useful tool for eliciting alcohol intake in clinical settings, particularly as this may improve self-reported veracity (see Chapter 6). Further research could compare the TOT-AL with conventional measures of alcohol consumption used in a number of different contexts, such as general practice or the emergency department. The TOT-AL could also be adapted to provide patients with feedback on their drinking – a key component of brief interventions for alcohol-related problems (Bien et al. 1993).

## Chapter 5: Incentives to reduce attrition from an online trial (DYD RCT)

– two randomised controlled trials

### ***Chapter overview***

Low rates of follow-up are characteristic of online trials and present an important methodological challenge in the evaluation of Internet-based interventions over the Internet. Low rates of follow-up reduce the power of analyses by reducing sample size and increase the possibility of bias. The use of incentives in online trials may improve follow-up without compromising the anonymity of study participants. Incentives have been found to improve response rates to cross-sectional postal and electronic surveys, yet few studies have investigated whether they can reduce attrition from follow-up in online trials. This chapter reports on two sequential randomised controlled trials that aimed to determine the effect of incentives at improving follow-up in the Down Your Drink online trial. It explores the types of incentives that may be attractive to the non-responders in this trial, and considers the cost implications of offering incentives to large numbers of trial participants. The ethical issues surrounding the use of incentives to boost research participation is also discussed, as this is a controversial issue.

### ***Background***

A limitation of the research on brief interventions delivered in-person or as self-help resources is that it lacks generalisability to the population of interest (Cunningham & Van Mierlo 2009; Kypri 2007; Kypri & Cunningham 2008). Where an intervention is intended for delivery over the Internet, online trials provide a pragmatic approach to determining their effectiveness in a naturalistic setting. The Down Your Drink online trial demonstrated

high external validity by recruiting participants who were searching the Internet for help to reduce their drinking. The results therefore generalise to the setting and population for which the intervention was intended, and as such, help inform service provision. However, there is a trade-off between external and internal validity (Kypri 2007). Online trials are particularly vulnerable to high rates of attrition (Eysenbach 2005). Follow-up rates as low as 15% and 35% have been reported at follow-up in online trials of web-based health promotion interventions (Bull et al. 2004; Etter 2005). Reasons for the high attrition rates in online trials are unknown. There could be a variety of explanations, such as the ease of entering and leaving an online trial in comparison with a conventional 'offline' trial, having little or no direct contact with the research team, or limited or non-usage of the intervention (Eysenbach 2005). Interviews with DYD trial participants (see Chapter 6) found that they tended not to distinguish between the trial assessment measures and the website as a whole and were not always aware they were participating in a trial. Reasons for not completing follow-up questionnaires in the DYD trial included participants having not changed their drinking behaviour, or that completion of the TOT-AL was irrelevant if they were no longer drinking alcohol (see Chapter 6). In the absence of these data at the time of the DYD trial, the use of incentives was considered as a way of improving follow-up.

Attrition from follow-up is a major methodological challenge in randomised trials and the proportion of participants who provide follow-up data is a recognised quality marker (CONSORT 2010; Medical Research Council 1998). Poor follow-up rates reduce the power of analyses by reducing sample size. They may also introduce non-response bias, where the likelihood of providing follow-up data is related to the outcome under study (Singer & Bossarte 2006), for example, if non-responders in an alcohol intervention trial tended to reduce their drinking less than responders, the treatment effect could be overestimated. The strength of this relationship and the proportion of non-responders will influence the size of the bias (Singer & Bossarte 2006). Of further concern in trials is

differential non-response between experimental conditions (as observed in the DYD RCT, see Chapter 3). This may undermine randomisation to create systematic differences between comparison groups and thus produce selection bias (Doody et al. 2003), for example, if those participants who found the intervention arm ineffective were more likely to drop out, then the treatment effect may be overestimated. Both these sources of bias can be minimised by high follow-up rates, but not necessarily eliminated.

One approach to improving follow-up in trials is through the use of incentives. A substantial literature shows incentives to be effective at increasing response rates in cross-sectional surveys (Edwards et al. 2009; Simmons & Wilmot 2004; Singer et al. 1999). A systematic review of methods to increase response rates to postal and electronic questionnaires found that offering a monetary incentive (defined as cash or cheque) nearly doubled the odds of response to postal questionnaires (odds ratio = 1.87; 95% CI: 1.73, 2.03) (94 trials), but no effect was found with electronic questionnaires (1 trial). Non-monetary incentives (such as gift vouchers or lottery participation) were found to increase the odds of response to postal questionnaires by over a tenth (odds ratio = 1.15; 95% CI: 1.08, 1.22) (94 trials), and nearly doubled the odds of response to electronic questionnaires (odds ratio = 1.72; 95% CI: 1.09; 2.72) (6 trials) (Edwards et al. 2009). Improved response with both monetary and non-monetary incentives has been reported in other reviews of postal, face-to-face and telephone surveys (Simmons & Wilmot 2004; Singer et al. 1999). Varying the value of non-monetary incentives was not found to influence response to postal (7 trials) and electronic questionnaires (7 trials), although low value comparisons were generally made (e.g. US\$1 vs. US\$2) (Edwards et al. 2009). Unconditional incentives (i.e. those provided regardless of response) improved the odds of response to postal questionnaires by over a half compared with incentives conditional on response (odds ratio = 1.61; 95% CI: 1.36, 1.89) (24 trials), whereas no difference related

to conditionality was reported with electronic questionnaires (3 trials) (Edwards et al. 2009).

It is not clear whether these data on improving response to cross-sectional surveys generalise to boosting follow-up in trials, particularly online trials, as there are relatively few studies examining this question. In a trial of antibiotics to improve neonatal outcomes after pre-term labour, a £5 gift voucher increased the return of postal questionnaires by 11.7% (95% CI: 4.7%, 18.6%; 42.3% follow-up rate with incentive, 30.6% follow-up rate with no incentive) (Kenyon et al. 2005). These findings were echoed in a trial of neck injury management, where a £5 gift voucher was found to be more effective than no gift voucher at increasing the proportion of returned postal questionnaires (75.7% vs. 68.7% respectively) (difference = 7%; 95% CI: 3%, 11%) (Gates et al. 2009). A trial of a web-based program designed to promote healthy eating evaluated 24 different combinations of values and conditionality of monetary incentives to promote recruitment and retention (Alexander et al. 2008). The optimal incentive combination was a US\$2 unconditional incentive for enrolment and promise of US\$20 (conditional incentive) on completion of follow-up measures. The highest rate of retention was achieved with the highest value of incentive. This research incentivised recruitment in addition to retention. The trials presented in this chapter are the first to investigate the impact of incentives on follow-up in an online trial, according to a systematic review of the impact of incentives for improving follow-up in trials that is currently underway (personal communication, Valerie Brueton, UCL, May 2011).

The cost implications of using incentives to improve follow-up has also been investigated (Brealey et al. 2007; Gates et al. 2009). Gates et al. calculated a cost of £67 per additional questionnaire returned in their study of neck injury management, discussed above. An observational study, embedded in a trial of treatment for knee problems, found

the cost of providing an unconditional incentive of £5 at twelve month postal follow-up was £48 per additional postal questionnaire returned (Brealey et al. 2007). Both studies concluded this cost to be a negligible increase in research budgets. In online trials, the cost of sending email reminders for completion of online measures is low. Unlike postal or telephone surveys, an incentivised increase in follow-up is unlikely to counter the cost of email reminders. The use of incentives in online research is an additional expense and requires a trade-off between improving response rates and the cost of research. Online trials have the capacity to recruit large numbers of participants relatively easily (Murray et al. 2009), and therefore even low value incentives may have a substantial impact on research budgets.

As demonstrated above, there is a lack of empirical research on the impact of incentives on follow-up rates in online trials, thus indicating the need to evaluate different incentive values and types before using them to boost follow-up in the DYD trial. This chapter reports on two sequential randomised controlled trials that aim to determine the impact of incentives on follow-up rates in the Down Your Drink online trial. Both incentive studies were embedded in the Down Your Drink online trial (pilot and main trial) (Murray et al. 2007; Wallace et al. 2011) (see Chapter 3). The Down Your Drink research team anticipated that follow-up rates would prove an important methodological challenge early in the piloting phase, and a number of initiatives were taken to improve retention to the trial. The DYD team emphasised the importance of completing follow-up measures in the participant information pages, consent form and trial newsletters. Participants were randomised to one of four secondary outcome measures to reduce measurement burden (see Chapter 3). Vigorous follow-up included up to three email reminders at weekly intervals, in addition to postal or telephone reminders for those providing optional offline contact details (see Chapter 3). Despite these attempts, five months into the DYD pilot study follow-up rates were low, i.e. 37% at 3 months: 19% after 1<sup>st</sup> email request for follow-



up, 11% after 2<sup>nd</sup> email request and 7% after 3<sup>rd</sup> email request. It was at this point that the first of the two incentives studies reported in this chapter was initiated with DYD pilot trial participants. If the results of incentive study 1 had shown a significant improvement (determined as 6% by the DYD research team) in follow-up rates with an incentive, then their use would have been considered in the main DYD RCT along with their affordability.

### ***Aims and objectives***

The principal aim of both incentive studies was to determine the effectiveness of incentives at improving follow-up in an online trial. The primary hypothesis in both studies was that offer of incentive would increase the follow-up rate compared with no offer of incentive. Secondary objectives were to determine the relative effectiveness of three different types of incentive (study 1 only), to identify predictors of response to incentives, and to calculate the cost of achieving an additional response.

### ***Methods***

#### **Sample size**

The sample size provides the minimum number of participants needed to reliably test the null hypothesis, that there is no difference in effect between experimental groups. The following data are needed for calculating a sample size: power of the hypothesis test, clinically important difference between experimental groups, and significance level. The power indicates the probability that a Type II error is not found, where a Type II error is the acceptance of a false null hypothesis. A clinically important difference between experimental groups is informed by clinical expertise and the literature. The significance

level indicates the extent to which a difference in experimental groups may be due to chance.

For both incentive studies, the DYD statisticians calculated a sample size to detect a 6% difference in follow-up rates between incentive and no incentive arms with 90% power at 5% significance level. The follow-up rate in the no incentive arm was taken as 11% for study 1 (based on DYD pilot study follow-up rates before the incentives studies commenced) and 26% for study 2 (building on the results of trial 1). This gave total sample size requirements of 1,468 for trial 1 and 2,400 for trial 2.

## **Participants**

In both incentive studies, participants were people already enrolled in the DYD trial and as such, had sought help online to reduce their drinking (Murray et al. 2007; Wallace et al. 2011) (see Chapter 3).

## **Intervention**

### *Study 1*

Preliminary research was undertaken to identify a range of potentially effective incentives. This included the identification of commonly used incentives in the survey literature (Edwards et al. 2009), discussion with the DYD RCT user representative, and a survey with a convenience sample that was demographically similar to the target audience of non-responders in the DYD trial. One of the challenges in determining which incentives would be most attractive to the non-responders in the DYD trial was that by definition, they were unlikely to respond to a request for their incentive preferences. Many of the non-responders in the DYD trial were young men; it was therefore important that the incentives

appealed to this demographic. A brief survey was conducted with colleagues and acquaintances (n=16) in order to gain some insight into the incentive preferences of young men. The survey asked people to choose their preference from three commonly used incentives in survey research (i.e. £5 Amazon voucher, charity donation or prize draw for iPhone or other prize), or to specify others. There was no outright preference for any of these incentive options among the ten people that responded to the survey; this resulted in the use of all three incentives for the initial study.

- Amazon.co.uk is one of the most popular websites in the UK, with online shopping a common use of the Internet (Dutton et al. 2009).
- Charitable donations have been widely used to incentivise survey response (Edwards et al. 2009). Cancer Research UK was chosen as it represents the nation's biggest fundraising charity, with 1 in 3 people in the UK affected by cancer (Cancer Research UK 2007).
- Entry into a prize draw was another widely used incentive, which was likely to cost less overall if found to be effective. A cash prize of £250 was offered to participants rather than a particular item (e.g. iPhone), as no one item was likely to appeal to all participants.

The survey literature suggested that both monetary and non-monetary incentives were effective at improving response. The type of incentive investigated in this study was governed by the participant group. Alcohol misuse is a stigmatised behaviour, and participants in the DYD trial valued their anonymity (see Chapter 6). Monetary incentives would have required participants to reveal their name and postal address, allowing a cheque to be issued and posted to them. An electronic Amazon.co.uk voucher code, on the other hand, could be emailed to a participant without requesting their 'offline' contact

details, such as postal address or telephone number. Participants could also be informed of charity donations and prize draw entry via email.

The literature suggested that the correct value of incentive improved response rates. Incentives that are too low may undermine the altruistic nature of the participant, and hence have a negative effect on response rates. In light of the findings from the survey and trial literature (Edwards et al. 2009; Gates et al. 2009; Kenyon et al. 2005), the value of the incentives used in the first incentive study was £5 (€6 / US\$7) for the Amazon.co.uk voucher and charitable donation, and £250 (€301 / US\$366) for the prize draw.

### *Study 2*

The results of study 1 informed the decision on value and type of incentive used in study 2. The results of incentive study 1 were inconclusive. Although collectively the three incentive types did not appear to increase follow-up compared with no incentive, the Amazon.co.uk voucher did lead to a slightly higher follow-up rate (non-significant). This led to the conception of incentive study 2, where a higher value Amazon.co.uk voucher of £10 was offered to participants. In both incentive studies, offer of an incentive was compared with no offer of incentive.

### **Procedure**

Participants were not informed about the potential offer of an incentive when registering for the DYD trial as this may have interfered with the process of informed consent by inducing people to take part. Prior knowledge of incentives may also have encouraged multiple registrations; in an online trial, with no face-to-face contact with trial participants, re-registration is an important concern (Murray et al. 2009). Registration to the DYD trial was

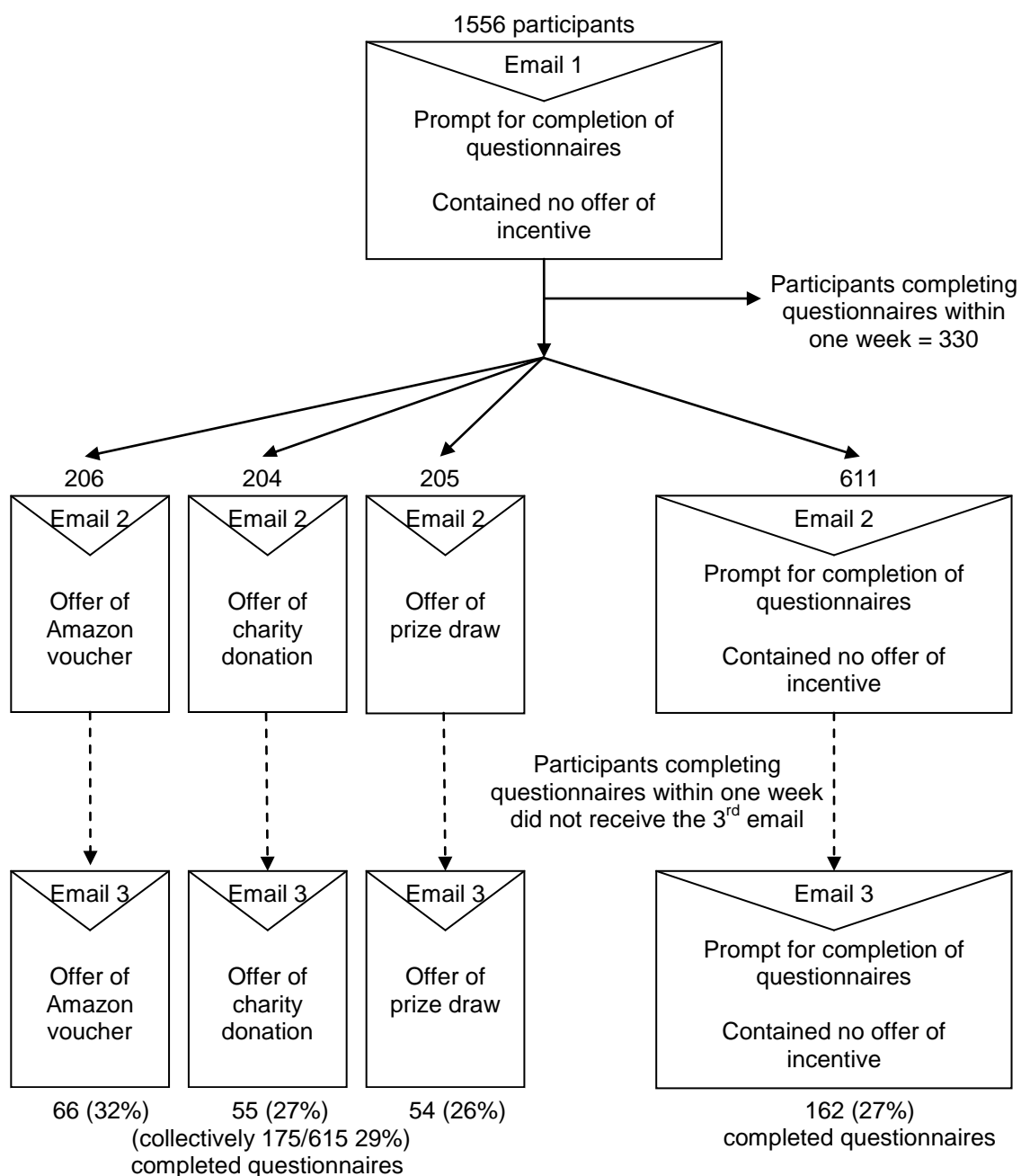
limited to an individual email address, yet many people have more than one email address and it is relatively easy to acquire additional email addresses.

Incentives were offered at the final point of follow-up in both the DYD pilot trial, i.e. 3 months (incentive study 1), and the DYD main trial, i.e. 12 months (incentive study 2). This was to limit any expectation of an incentive on completion of follow-up questionnaires, which may have had a detrimental effect on subsequent follow-up rates had no incentive been offered.

### *Study 1*

The follow-up procedure for the DYD trial consisted of up to three email reminders at weekly intervals. In study 1, DYD pilot trial participants were emailed a request to provide follow-up data at three months (between 21/9/2007 and 15/1/2008). The email contained a hyperlink to the study questionnaires, stressed the importance of providing follow-up data, and conveyed the team's gratitude to the participant for completing the measures. Those participants who had not completed the outcome measures one week after the first email request were randomised to receiving an offer of an incentive or no offer of an incentive (see Figure 17). Study 1 was thus restricted to those participants who did not respond to the initial request to provide follow-up data. The decision to offer incentives to non-responders to the first email request for follow-up data was financially motivated. Resources for incentives were limited and the trial was recruiting large numbers of participants (around 60 / week). A follow-up rate of 19% was observed after the first email request for follow-up. Offering incentives in the second and third email requests therefore saved money. This decision did however come with ethical concerns. Offering an incentive to non-responders to the first email request for follow-up could be conceived as rewarding 'delinquent' behaviour.

**Figure 17. CONSORT flowchart – study 1**

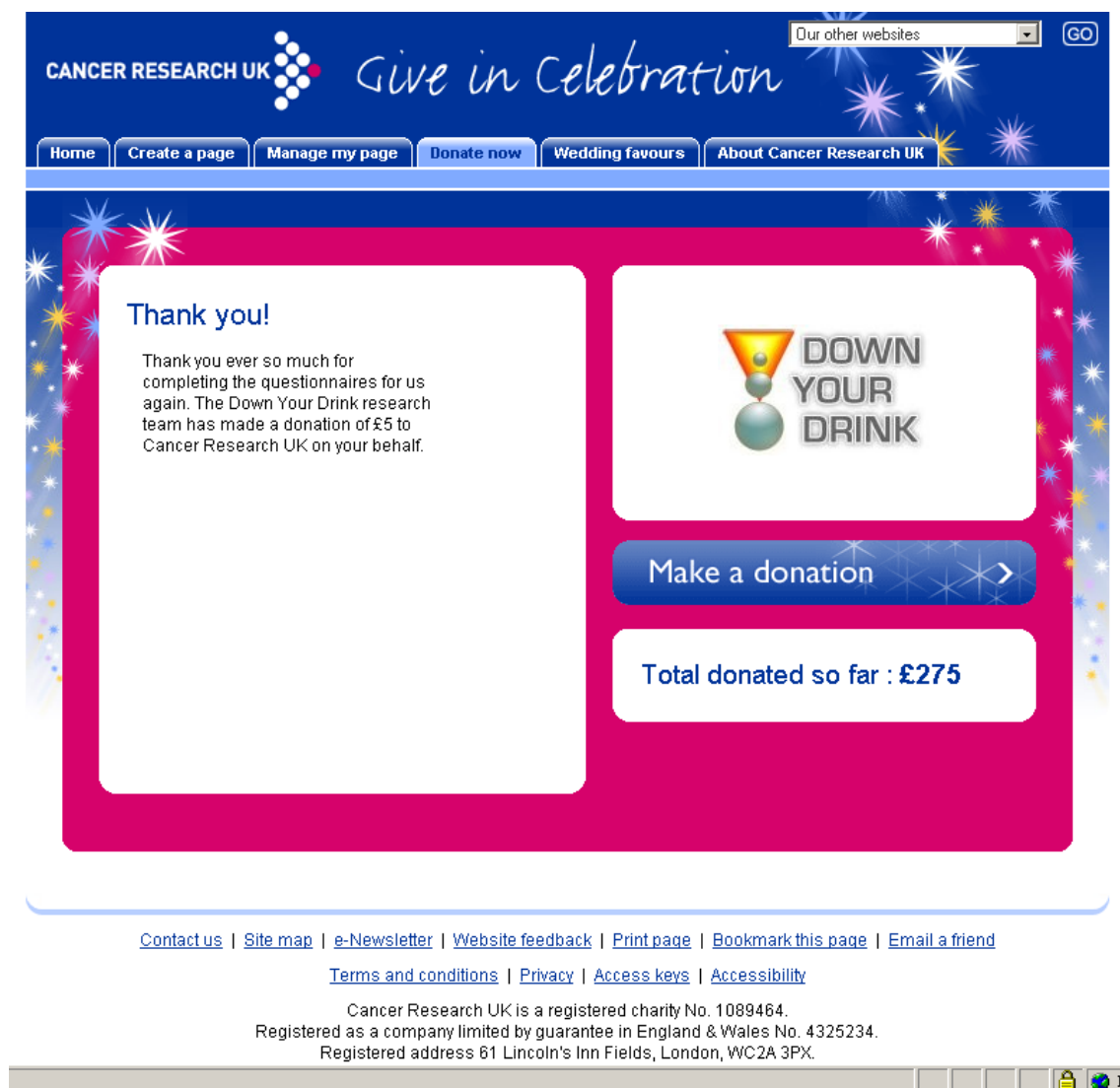


Within the incentive arm, participants were also randomly allocated to receive either the £5 Amazon.co.uk voucher, £5 donation to Cancer Research UK, or entry to a £250 prize draw. Offer of incentive was given in the second and third email prompts (see Figure 17).

The email prompts offered incentives as a token of appreciation for the participant's time, as opposed to an incentive for response.

An online, password protected, database was constructed to facilitate the conduct of these studies. It contained the email address of each participant included in the studies, their allocated arm, whether or not they had completed the questionnaires, and where applicable, the date and time that completion had taken place. Participants responding in each incentive arm were sent an email (personally generated) which thanked them for their time and contained, as appropriate: a unique Amazon.co.uk voucher code and instructions on how to claim, a hyperlink to the charity's website which detailed the amount donated to Cancer Research UK as a result of participants completing the questionnaires (see Figure 18), or confirmation of prize draw entry for £250. The dates on which these emails were sent were recorded in the database, along with the Amazon voucher code where applicable. Anonymity was maintained by sending Amazon.co.uk voucher codes by email rather than requesting a postal address.

**Figure 18. Screen shot of charity donation confirmation page**



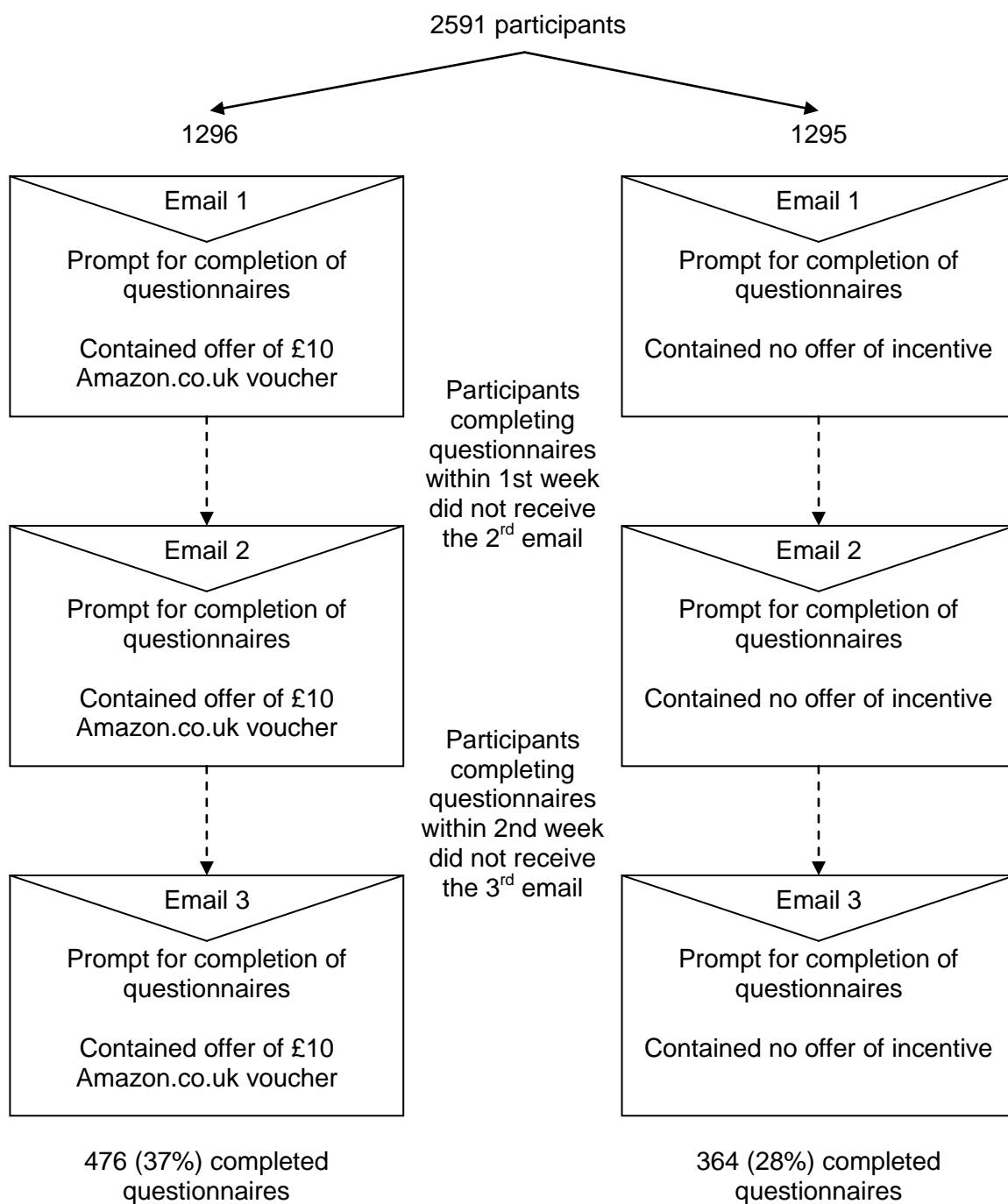
## *Study 2*

The results of study 1 informed the decision on value and type of incentive used in study 2. In study 2, all DYD RCT participants were randomised to receive either an offer of an incentive (£10 Amazon.co.uk voucher) or no incentive at the first request for data at the final (12 month) follow-up (between 26/11/2008 and 1/9/2009) (see Figure 19). All participants received up to three email reminders with requests for provision of follow-up data. Each reminder contained a hyperlink to the study questionnaires, stressed the



importance of providing follow-up data, and expressed the team's gratitude to participants for their time. In addition, participants in the incentive arm were informed they would be sent a £10 Amazon.co.uk voucher on receipt of their completed study questionnaires. A further email with a unique Amazon.co.uk voucher code was sent on completion of questionnaires (personally generated).

**Figure 19. CONSORT flowchart – study 2**



In both studies, randomisation was performed by a computer generated randomisation sequence that triggered automatic emails to participants. Hence, randomisation could not be subverted by the study team and allocation was thus fully concealed. Randomisation

was stratified by DYD experimental group (DYD intervention vs. DYD comparator). The randomisation function in Java was used to generate random assignment.

## **Outcomes**

In both studies the outcome was the proportion of participants who responded – defined as completing the questionnaires within 40 days of the first email reminder after randomisation. Additional data already obtained at entry into the DYD trial, including age, gender, baseline weekly alcohol consumption and DYD experimental group (intervention or comparator), were used to explore possible variability in outcome.

Data gathered for the economic analysis included the cost of developing the database for each study, the time spent sending personalised emails, and the cost of the incentives themselves.

## **Analyses**

The primary analysis compared follow-up rates between the no incentive arm and incentive arm (three incentive arms combined for the first study). For study 1, secondary analyses explored the differences between incentive types. Statistical significance was calculated using chi-squared tests.

Subgroup analyses were conducted for gender, age and heavy drinking at baseline (>35 / 50 units per week for women / men respectively, where 1 unit = 8g ethanol). Interactions between these variables and allocation to incentive in affecting follow-up rates were tested on a risk difference scale using the binreg command in STATA. The statistical analyses were undertaken by EK and IW in STATA version 10.

A simple economic analysis was conducted for both studies. It cost £822 to set up a database for the research for study 1 and £1,180 for study 2. Identifying which participants completed the questionnaires and were therefore eligible to receive an incentive or not, and sending emails to deliver the incentive took 10 minutes per 10 participants at a cost (including overheads) of 95p per minute. In practice, offering incentives would involve some but not all of these costs. For example, if all participants were offered an incentive, then some of the selection and computer programming time would be saved. As the purpose of the economic evaluation was to compare the additional costs of incentives compared with the control condition of no incentives, a reasonable estimate of the additional set-up costs was 50% of the database costs plus an additional minute of researcher time per incentive offered. The final costs of the scheme were those of the incentive. The cost effectiveness ratios were calculated as the additional cost per successful additional completed follow-up, i.e. the total cost of offering incentives divided by the number of additional responses.

## ***Results***

### ***Study 1***

A total of 1,226 participants were randomised to receive an offer of incentive (n = 615) or no offer of incentive (n = 611) (Figure 17). The characteristics of participants randomised to each study arm were similar (Table 7). There was no significant difference in follow-up rates between participants who received an offer of incentive (175/615; 29%) compared with those who did not receive offer of an incentive (162/611; 27%) (difference 2%, 95% CI -3% to +7%), nor was there any significant difference in follow-up rates between the three incentive arms (Amazon.co.uk voucher = 32%, charity donation n = 27%, prize draw n = 26%; P=.37) (Table 8). There were no significant interactions with gender, age and heavy drinking at baseline.

The costs associated with offering incentives in study 1 are outlined in Table 9. The incremental cost per successful follow-up in the incentive arm was £110 (£1,432 total cost / 13 additional responses).

### *Study 2*

A total of 2,591 participants were randomised to receive offer of a £10 Amazon.co.uk voucher (n = 1,296) or no offer of incentive (n = 1,295) (Figure 19). Characteristics of participants randomised to each study group were similar (Table 7). There was a 37% follow-up rate (476/1,296) among those participants that received offer of a £10 Amazon.co.uk voucher, compared with a 28% (364/1,295) follow-up rate among those who did not receive an offer of incentive (difference 9%, 95% CI +5% to +12%,  $P < .001$ ; Table 8). There were no significant interactions with the three baseline variables considered.

The incremental cost per successful follow-up in the incentive arm was £52 (£5,802 total cost / 112 additional responses) (Table 9).

**Table 7. Baseline characteristics of participants in study 1 and 2**

		<b>Incentive</b>	<b>No incentive</b>
<b>Female %</b>	Study 1	54	54
	Study 2	58	59
<b>Age (years) Mean (SD)</b>	Study 1	37 (11)	37 (11)
	Study 2	38 (11)	38 (11)
<b>Baseline drinking (UK units) Mean (SD)</b>	Study 1	56 (37)	59 (42)
	Study 2	59 (37)	57 (42)
<b>DYD intervention arm %</b>	Study 1	51	51
	Study 2	50	50

**Table 8. Follow-up rates for incentive groups in study 1 and 2**

	Incentive group	Total randomised	No. of responses	Response rate	Difference	95% confidence interval
<b>Study 1</b>	Incentives (collectively)	615	175	28.5%	2%	–3% to 7%
	No incentive	611	162	26.5%		
	£5 Amazon voucher	206	66	32%		
	£5 charity donation	204	55	27%		
	£250 prize draw	205	54	26%		
<b>Study 2</b>	£10 Amazon voucher	1,296	476	37%	9%	5% to 12%
	No incentive	1,295	364	28%		

**Table 9. Costs associated with offering incentives in study 1 and 2**

		<b>Cost per person</b>	<b>Total cost</b>
<b>Study 1</b>	Setting up database	0.67p per person	£411
	Time sending confirmatory incentive email (per completed questionnaire)	0.95p per person	£166
	Incentive		
	Amazon voucher	£5 (x66)	£330
	Charity donation	£5 (x55)	£275
	Prize draw	£250	£250
	Total		£1432
<b>Study 2</b>	Cost per extra follow-up response		£110
	Setting up database	0.46p per person	£590
	Time sending confirmatory incentive email (per completed questionnaire)	0.95p per person	£452
	Incentive (Amazon voucher)	£10 (x476)	£4760
	Total		£5802
	Cost per extra follow-up response		£52

## ***Discussion***

The types and value of incentives offered in study 1 were comparable to those shown to have a positive impact on improving response rates to postal and electronic surveys (Edwards et al. 2009) and on improving follow-up rates in trials (Gates et al. 2009; Kenyon et al. 2005). However, collectively, the incentives used in study 1 did not improve follow-up. In a trial of a health promotion website, the highest rate of retention was achieved with the highest value of incentive (US\$20 / £13) (Alexander et al. 2008). The findings of study 2 mirror this result. The lower value incentives offered in study 1 may have been more effective if participants could have chosen a charity of their choice, or if the winning participant of the prize draw was not required to break their anonymity to claim the money. Nevertheless, the results of study 1 were inconclusive, as discussed below, and further research is necessary to replicate the findings of these trials in low value incentives.

The cost per additional response in study 1 was double that of study 2 (£110 vs. £52 respectively). Previous studies providing a £5 incentive unconditional on response estimated costs similar to study 2 (£67 and £48) (Brealey et al. 2007; Gates et al. 2009). One explanation for the effectiveness of lower value incentives in the previous literature



could be that they were provided unconditional on response (Brealey et al. 2007; Gates et al. 2009; Kenyon et al. 2005). The survey literature suggests that unconditional incentives may be more effective than those conditional on completion of measures (Church 1993; Edwards et al. 2009; Simmons & Wilmot 2004). An incentive that is conditional on response leads to an economic rather than a social exchange. In this situation, an incentivised request to complete follow-up is easily declined if deemed of low value. On the other hand, incentives unconditional on response, sent as good will gestures, can lead to reciprocal obligation (Dillman 2000). The decision to promise an incentive on completion of the questionnaires, rather than provide them unconditionally, was done for two reasons. The first was financial: online trials have the potential to recruit large numbers of participants (the DYD trial recruited 7,935 people). If incentives were provided unconditionally to the entire sample there would be substantial cost implications and without the evidence to support this decision the expense could not be justified. The second reason was methodological: providing unconditional incentives from the outset of the DYD pilot study might have encouraged multiple registrations to the trial. In an online trial, with no face-to-face contact with trial participants, re-registration is a relevant concern (Murray et al. 2009).

The use of incentives in research is controversial. They are often criticised for being coercive or for providing undue inducement. "Coercion is an extreme form of influence by another person that completely controls a person's decision"; furthermore, it "deprives the person of autonomous choice, and thus is incompatible with informed consent" pp. 338-339 (Faden & Beauchamp 1986). An incentive that is offered to a participant is not coercive as it may be accepted or refused (Erlen et al. 1999). An inducement may be considered undue if it encourages a person to take part in research against their better judgement, e.g. if it puts them at risk of harm (Emanuel 2004). This may occur in persons of lower socioeconomic status where the value of incentive is too good to refuse.

However, it has been argued that to receive ethical approval, a study should demonstrate that it does not put the participant at risk of harm. Certainly the completion of follow-up questionnaires was not envisioned to cause DYD participants any harm. The use of incentives in the DYD trial did not interfere with the process of informed consent. Participants self-recruited to the trial and provided consent to complete follow-up questionnaires at study entry without any knowledge of incentives. The decision to participate was not influenced by the offer of incentives, rather, incentives were offered at follow-up as a 'token of appreciation' for completing the questionnaires. The offer of incentives at follow-up may have influenced the type of people responding to the questionnaires. There were no significant predictors of non-response, yet variables were limited to gender, age and heavy drinking at baseline.

Another ethical concern was that participants were randomised to different incentive groups without their consent. This was justified in that those participants randomised to the no incentive arm had the same experience as those enrolled in the DYD trial before the incentive study began, while those randomised to the incentive arm had the additional benefit of being offered an incentive.

Altruism is a commonly cited motive for trial participation (Prescott et al. 1999; Ross et al. 1999; Todd et al. 2009), where participants take part in research for the benefit of others regardless of any benefit for themselves. There is a concern that the use of incentives may undermine altruistic reasons for participation and have a detrimental effect on follow-up rates. The evidence for altruism as a motivating factor for trial participation is strongest in cancer trials and may not translate to this population of hazardous and harmful drinkers seeking help online. There is also some evidence that altruistic motives are often accompanied by self-interest (conditional altruism), where participants are happy to help others if there is also some benefit for themselves in taking part in the trial (Canvin &

Jacoby 2006; Edwards et al. 1998; McCann et al. 2010). These motivations have also been reported in the limited literature on trial retention, where participants are thought to remain in trials for personal benefit (i.e. access to better treatment), as well as commitment to the trial and to help others (Nakash et al. 2008; Wendler et al. 2008). Altruism is unlikely to have played a major role in the DYD RCT, where participants self-recruited to the trial in order to access help to reduce their drinking. Further research is needed to determine motives for entering and remaining in online trials, and how this may impact on the use of incentives.

A potential limitation of the first incentive study is that it failed to meet its planned sample size because the DYD pilot phase ended slightly earlier than anticipated (due to programming commitments necessary for the commencement of the main DYD-RCT) and due to an error in the sample size calculation. Before the incentive studies took place, the follow-up rates in the DYD pilot trial were 19% after the first email request, 11% after the second email request and 7% after the third email request. In incentive study 1, participants in the incentive arm received offer of incentive in emails 2 and 3. The assumption of an 11% follow-up rate was incorrect; the sample size calculation should have assumed a follow-up rate of 18% in the no incentive arm (11% + 7%). If a follow-up rate of 18% had been assumed in the sample size calculation for study 1, then the estimated sample size would have been substantially larger. This helps explain why the 95% confidence intervals were wide despite almost achieving the planned sample size. For this reason, and because follow-up rates in the control arm were higher than expected, the results of study 1 were somewhat inconclusive, with a confidence interval including both no difference and the 6% difference in follow-up specified in the power calculation.

The conclusions are strengthened by the large sample sizes employed, the randomised design, and the completeness of the data. The results from the first study were used to

inform the design of the second study. The £5 Amazon voucher in study 1 resulted in the highest follow-up rate of the three incentive types (although it was not higher to a statistically significant degree). The second study then randomised participants to a higher value incentive (£10 Amazon voucher). Study 2 was undertaken in a population and setting that was similar to study 1; the main differences being that study 1 was conducted in pilot DYD trial participants at 3 months who had not responded one week after an email request for follow-up, whereas study 2 was conducted with all main DYD trial participants eligible for 12 month follow-up within a defined time period.

### ***Conclusion***

These were two of the first trials of the use of incentives for improving follow-up in an online trial. Promise of a low value incentive (£5 Amazon.co.uk voucher, £5 charity donation, or prize draw for £250) had no significant impact on follow-up rates, whereas promise of a higher value incentive (£10 Amazon.co.uk voucher) improved follow-up rates by 9%. It should be borne in mind, however, that direct comparisons between the two studies are limited by differences in the study populations (those not initially responding in study 1 versus all respondents in study 2) and follow-up study time frames (3 and 12 months respectively). Notwithstanding these caveats, the higher incentive was also more cost-effective, in terms of costs per additional response. Future trials should not assume that any value of incentive will improve follow-up rates.

### ***Further research***

Further research should explore different values of different types of incentives for improving follow-up in online trials of heavy drinkers. The challenge is to determine the preferences of non-responders, when by definition this group is difficult to access. Further

research should consider the types of people attracted to incentives and whether incentives can reduce non-response bias in addition to improving response rates. The impact of socioeconomic status on the effectiveness of incentives needs to be investigated, along with possible cultural differences in receptivity. Differences in the quality of data from incentivised and non-incentivised participants would also be of interest. Conditional offers of incentives could be compared with the unconditional provision of incentives, provided this does not encourage multiple registrations. The costs of offering incentives can be substantial, and whether such costs are a good use of research funds should also be considered.

Beyond the use of incentives, it is also important to determine the underlying reasons for attrition, and how the online trial context may relate to this. For example, is it harder to establish rapport between participant and researcher over the Internet? And does this affect the participant's commitment to the trial? One of the major benefits of online trials, particularly those of heavy drinkers, is that the participant retains their anonymity. Further research is needed into improving follow-up without the divergence of any personal identifying information, such as postal addresses or telephone numbers. Research into the impact of spam filters on follow-up rates and methods of avoiding them would also be of benefit to this field.

## Chapter 6: User's experience of an Internet-based intervention (DYD) for reducing alcohol intake and taking part in an online trial (DYD RCT) – qualitative interviews

### ***Chapter overview***

DYD trial participants represented a previously unstudied sample of adults from the general population who were drinking at hazardous and harmful levels, and searching the Internet for help or information on their drinking. Participants randomised to the DYD intervention arm were also unique in their experience of accessing a novel intervention for reducing their drinking. Previous qualitative research in the alcohol field has focussed on dependent drinkers seeking specialist in-person treatment. The aim of this chapter was to explore people's experience of searching for help online to reduce their drinking, of using an Internet-based intervention (DYD) and of taking part in an online trial (DYD RCT). The qualitative interviews presented in this chapter provide an illuminating insight into the help seeking experience of DYD trial participants, with themes including problem recognition, type of help wanted, barriers to formal help seeking, and in-person and self-help resources accessed. Participant experiences of using the DYD intervention, control and trial areas of the website were also explored. A key challenge with Internet-based interventions is getting people to access and engage with them. Exploring the user's perspective is vital in achieving this and in shaping future services according to the user's needs.

### ***Background***

There is a clear demand for Internet-based interventions for reducing alcohol consumption among the general population, as demonstrated by the large number of visitors to the DYD

website (see Chapter 3) and similar websites in Canada, the US and the Netherlands (Cunningham et al. 2000; Murray et al. 2009; Riper et al. 2009; Saitz et al. 2004). The evidence that these interventions can assist users in reducing alcohol intake is mounting, particularly in student samples (Carey et al. 2009; Khadjesari et al. 2011; Rooke et al. 2010; White et al. 2010) (see Chapter 2). What is lacking from the literature is an insight into the user's experience of using an Internet-based intervention for reducing their drinking that gauges whether these interventions meet user needs. This research is particularly vital for the optimisation of stand-alone interventions without therapeutic guidance. Once an intervention is made available online, it can be accessed by anyone seeking help over the Internet, unlike the numerous barriers that face the delivery of brief interventions in-person. However, a key challenge faced by all Internet researchers is ensuring that people access and engage with the intervention. Attrition from Internet-based interventions is common, suggesting that users may not be using them as intended (Christensen et al. 2006; Cunningham et al. 2009; Eysenbach 2005), or that the interventions are not meeting their needs. The qualitative interviews presented in this chapter provide a suitable research technique for gaining a detailed insight into people's experience of using the DYD website, how it is used, what features people find helpful or unhelpful, and how it could be improved. This is important if DYD and future Internet-based interventions are to meet the needs of their users.

While there has been no qualitative research on people's experience of using an Internet-based intervention for reducing alcohol intake, there has been some exploration of user's preferences for the content and functionality of alcohol-related websites. Focus groups with a sample of Australian adults from the general population (n=51, nine groups) were conducted to determine expectations and preferences for alcohol and other drug-related websites (Kay-Lambkin et al. 2011). Participants had spent around 30 minutes searching the Internet for alcohol and other drug-related websites before participating in the focus

groups. Favourable features of the websites encountered by the participants included the provision of clear and concise information, non-judgemental tone, personalisation and interactivity, life experiences/stories, and the trustworthiness of the website. Participants felt the Internet was lacking information on prevention of harmful alcohol or other drug use, information on comorbidity, an online forum, and an online portal to recommended alcohol and other drug-related websites (Kay-Lambkin et al. 2011). Many of these participants also completed an online survey of Australian adults visiting alcohol (n= 448) and other drug-related (n=766) websites (Klein et al. 2010). This survey found that easy navigation, open access, and the correct amount of information were rated among the “very important” features of a website. Downloadable fact sheets, an online portal to websites and treatment options, online screening tests, and tailored information were rated as “very important” tools or functions of an alcohol website. The most frequently visited websites were those from trusted sources (e.g. Australian Government) (Klein et al. 2010). Most of the participants in this survey were young people (65% aged between 16-24 years old) seeking information on the effects of alcohol or other drug use. This study did not collect data on participant’s alcohol intake, and therefore it is unknown whether these findings represent the views of hazardous and harmful drinkers seeking help online. It should also be noted that this survey questioned participants about general and interactive websites, not Internet-based interventions (i.e. therapeutic interventions) (see Chapter 1: The Internet as an alternative mode of delivery).

There has been some research conducted with dependent drinkers seeking specialist in-person treatment into the reasons why people enter treatment for an alcohol problem. This has identified common antecedents to help-seeking, including problem recognition, negative or adverse consequences (e.g. in relation to health, family or work), accumulation of problems, symptoms of dependence, pressure or influence from others, and prior treatment experience (Finney & Moos 1995; Hartnoll 1992; Jordan & Oei 1989; Orford et



al. 2006b; Tsogia et al. 2001). Although DYD participants were also seeking help with their drinking, they differ from conventional treatment seekers. DYD participants were drinking an average of 46 units of alcohol per week, with low levels of dependence, but with several reported alcohol-related problems. They displayed some motivation for reducing their drinking in registering with the DYD website, and displayed some degree of self-efficacy and intention to change (as reported in Chapter 3). Conventional treatment seekers tend to exhibit more severe alcohol-related problems (Finney & Moos 1995; Hartnoll 1992; Tsogia et al. 2001) and high levels of motivation and readiness to change their drinking (Heather 1995), whereas non-treatment seekers experience less severe alcohol-related problems and lower levels of motivation (Moyer et al. 2002). The qualitative research in this chapter revealed further differences between this novel group of 'e-help seekers' (seekers of help online) and these conventional categories of alcohol misusers, uncovering an overlooked population with substantial unmet need.

Also of interest to this thesis is the experience of people taking part in an online trial. The DYD trial was one of the earliest randomised controlled trials to be conducted over the Internet in its entirety (Wallace et al. 2011). The online context of the trial had both advantages, such as the ease of recruitment and data collection, and disadvantages, such as low rates of follow-up (as discussed in Chapters 2 and 4). Possible explanations for these high drop-out rates, which are characteristic of online trials, include the ease in which participants enter and subsequently leave an online trial, limited contact with the research team, or limited use of the intervention (Eysenbach 2005). Qualitative research on the user's perspective, presented in this chapter, has provided additional explanations that may improve future online trial methodology. These qualitative interviews with DYD participants also helped illuminate the findings of the DYD trial, where participants in both experimental arms were found to significantly reduce their drinking.

## ***Methods***

### **Study aim and objectives**

To explore people's experience of searching for help online, using an Internet-based intervention (DYD) and taking part in an online trial (DYD RCT), with a view to understanding the role of Internet-based interventions in helping people reduce their alcohol intake.

Experience of searching for help online:

- To determine why participants sought help with their drinking online, and their reasons for choosing DYD;
- To determine the advantages and disadvantages of seeking help over the Internet.

Experience of using an Internet-based intervention (or comparator website):

- To discover whether DYD met participants' expectations;
- To learn which features of DYD were helpful or unhelpful and whether they impacted on drinking behaviour;
- To find out which features could be improved, added or removed;
- To investigate the use of other resources and their impact on drinking behaviour.

Experience of taking part in an online trial:

- To understand participants' reasons for entering the trial and to hear their views on the requirements of the trial;
- To determine the validity of the information provided and reasons for non-response;
- To discover ways of improving the trial website and the conduct of online trials.

## **Research design**

This was a qualitative study using semi-structured interviews with people who had participated in the DYD randomised controlled trial. The DYD trial recruited people over the Internet searching for help or information on their alcohol intake (see Chapter 3).

Ethical approval was granted from University College London (UCL) and University of York research ethics committees. The research was principally based at UCL, with interviews conducted at UCL and the University of York.

## **Sampling strategy**

Potential interviewees were people who had taken part in the DYD RCT. As such, they were aged 18 or over, drinking above recommended safe limits and interested in reducing their drinking. The DYD trial (pilot and main trial) ran from February 2007 until the end of May 2009. The interviewees in this qualitative study therefore varied in length of exposure to the Down Your Drink website (intervention or comparator) and recency of visit. The study intended to recruit a purposive sample that reflected a range of participant characteristics that may influence the effectiveness of an alcohol intervention. This was deemed important as these interviewees may have had different experiences. These characteristics were chosen according to the literature (Project MATCH 1997; Riper et al. 2008a) and were determined by the data available from the DYD-RCT: gender, education and alcohol consumption. Data on the interviewee's age and randomised arm (DYD intervention or control) were also collected. However, recruiting a purposive sample was not possible due to the small number of participants who volunteered to take part in the study and as such, a convenience sample was recruited.

## **Recruitment procedure**

Interviewees were recruited via the DYD trial newsletter and a banner on the DYD homepage. Those people expressing an interest in taking part in the interviews were sent (via email) a participant information sheet and consent form. Permission to use their data collected at baseline in the DYD RCT (variables listed above) was requested as part of the consent procedure. People were invited to talk about their experience of using Down Your Drink (both intervention and comparator arms) and being part of an online trial.

Interviewees were offered £25 to reimburse their time, and up to £50 for travel expenses. Participants who had withdrawn from the DYD trial were no longer in receipt of the trial newsletters and were unable to access the DYD website, so it is unlikely that they would have seen an advertisement for this interview study. Withdrawal from the DYD trial meant that participants did not want any further contact from the DYD team; it was therefore not possible to invite these participants for an interview. Those participants who had dropped out of the trial (i.e. failed to complete follow-up measures) would have received the newsletter and been able to access the DYD website.

## **Data collection**

Semi-structured interviews were conducted with DYD RCT participants between September and December 2009, after the trial had ended and all follow-up data had been collected. Interviewees were reminded of the aims of the study at the start of each interview. Interviewees were assured of their confidentiality and that no personal identifying information would be linked to any of the data they provided. Each interviewee was re-issued with the participant information sheet, asked if they had any questions and confirmed they had submitted a signed consent form. Interviewees were told there were no right or wrong answers, and that it was their personal opinions that were of interest. They were also reminded that they may pause or stop the interview at any point, without

giving a reason. Permission to record the interview was requested before commencing. Further questions were invited at the end of each interview.

It was possible that interviewees may have suffered considerably from their drinking. Discussing their reasons for using DYD might recall some unhappy memories and emotions. In the event that an interviewee became distressed or upset, there was a procedure in place to deal with the situation. This consisted of taking a break and waiting until they were ready to continue or discontinuing if they preferred to terminate the interview. This action was not needed for any of the interviewees in this study. A list of alcohol services and other helpful resources were offered to each interviewee on their departure. To avoid disappointment, the participant information sheet made it clear that the purpose of these interviews was to hear the participant's views and not to provide advice on their drinking. A safety procedure was put into place in the event that an interviewee turned aggressive. All interviews were conducted within university departments, where the departmental administrator held a list of those scheduled each day. The administrator was contacted at the beginning and end of each interview, and held the interviewers contact details in the event that contact was not made.

The original topic guide consisted of three broad topic areas: 1) seeking help via the Internet; 2) experience of using an Internet-based intervention (or comparator website); and 3) experience of taking part in an online trial. There were specific questions under each of these themes to address the objectives of the research. The interviews were designed to be semi-structured, where the topic guide served as prompts rather than a rigid guide. All interviews were started with the question, "How did you come across the DYD website?" as it could be easily answered. Interviewees could then take the interview in any direction they wished. An iterative approach was taken, where the interview data

helped develop and refine the topic guide and inform analysis with emerging ideas (for original topic guide see Box 2).

## Box 2. Interview topic guide

### Introduction

Thank interviewee for taking part in the research and introduce myself. Make sure they are comfortable and able to stay for up to one hour. Remind interviewee that they are here voluntarily and free to leave at any point. Confirm completion of consent form. Start recording.

### Opening statement

The purpose of this research is to hear your experience of using the Down Your Drink website and taking part in the online trial. There are no right or wrong answers, I just want to hear your opinions. The online trial you were involved in will tell us whether, on the whole, people using Down Your Drink reduced their drinking over time or not. But it tells us nothing of your individual experience of using the website. We think this information will help improve the future development of websites and online research studies.

Do you have any questions at this point?

### 1. Can you tell me a bit about how you came across the Down Your Drink website?

[Objectives]

- How did you find DYD and what were your reasons for looking for it?
- What are the advantages and disadvantages of the Internet setting?

### 2. Can you tell me what you thought of the Down Your Drink website?

[Objectives]

- Did DYD meet your expectations?
- Which features of DYD were helpful or unhelpful?
- Which features could be improved, added or removed?
- Did you use any other resources to cut down on your drinking?

### 3. Did you realise that you were part of a research study? What did you think about that?

[Objectives]

- What were your reasons for entering the trial?
- How did you respond to the needs of the trial?
- How would you have improved the conduct of the trial?

### 4. Is there anything else you'd like to talk about that we haven't covered?

### 5. Is there anything you would like to ask me?

### Close.

Thank interviewee for their time and valuable contribution, turn-off digital recorder. Provide the participant with reimbursement (obtain signature) and complete travel expense claim form.

Interviewees attended interviews at University College London, University of York, or over the telephone, according to their preference. Participants chose to be interviewed by telephone for geographical reasons when unable to access either of the chosen locations.

Greater transferability was achieved by having a wider geographical spread of interviewees. Telephone interviews have been criticised for the absence of visual cues, resulting in a lack of informal communication, rapport, contextual information and the possibility of misinterpretation. However, evidence to support these criticisms is limited and their impact on the quality of data is unknown (Novick 2008). Data from telephone and in-person interviews were combined as there were no perceived differences in their quality. Interviews typically lasted for around one hour and ranged from 25 to 105 minutes. The average face-to-face interview lasted 11 minutes longer than the average phone interview (56 minutes vs. 45 minutes, respectively). The interviews were digitally recorded and transcribed verbatim by a professional transcription company. Each transcript was checked for accuracy against the recording soon after it was received and any personal identifying information was removed, such as names and places. When presenting the data in this chapter, each quotation is followed by the participant number, gender, age, baseline alcohol consumption in units per week (as reported in the DYD-RCT), and DYD experimental arm (DYD intervention or DYD control). Field notes were taken directly after each interview to record non-verbal information. These helped to understand the context of the interview and to aid interpretation and analysis. For example, it was clear that attending interviews in-person was a challenge for some interviewees due to the stigma surrounding problem drinking.

### **Data analysis**

The data were analysed using a detailed thematic analysis (Braun & Clarke 2006). This process began by familiarisation with the data by reading the transcripts and listening to the interview recordings several times, and noting down areas of interest and potential codes. Initial codes were generated for as much as the data as possible and applied systematically to the corresponding text in the transcripts using Atlas.ti 6 – a software



package used to assist with the organisation of the data. Once the entire dataset was coded, data extracts were collated under each of these codes. The codes were then organised into broader themes and sub-themes (see Box 3). A proportion of transcripts were read and coded by two experienced researchers (EM and FS – see Acknowledgements), both with backgrounds in health service research, e-health and qualitative research. This helped refine the coding framework and resulted in additional themes. An inductive approach to analysis was taken, where themes were directly linked to the data (i.e. data-driven). This approach is suited to the exploration of experiences of a previously unstudied population (Braun & Clarke 2006). Themes were reviewed by re-examining corresponding data extracts, and un-coded, outlying data were examined for disconfirming evidence. An iterative process was taken, where the transcripts were revisited throughout the process of coding, theme allocation and written presentation.

### Box 3. Themes and sub-themes

1. Accessing help online Problem recognition Barriers to formal help seeking Stigma Labelling Advantages of Internet setting Disadvantages of Internet setting Anonymity Convenience	2. Gaps in service provision Type of help wanted Abstinence vs. moderation Grey area Focus on dependent drinkers AA only option
3. Using an Internet-based intervention (DYD intervention) Drinking Episode Calculator Blood Alcohol Concentration calculator Alcohol and Relationships Surfing urges Tips for cutting down Positive aspects Negative aspects Improvements Comparison with other websites	4. Using DYD comparator website
5. Use of other resources Self-help resources (i.e. bibliotherapy) Websites / blogs Specialist in-person treatment GP Application of other techniques – CBT Stepped care	6. Participating in an online trial Trial registration Self-reported veracity Reactivity of assessment Follow-up questionnaires

## Results

### Participant characteristics

A total of 18 people were interviewed: 10 women and 8 men. They had an average age of 43 years, ranging from 25 to 67 years. Most interviewees had a university degree qualification or above (n=11; 61%), two had A' levels or equivalent, four had O'levels or equivalent, and one had "Other Qualifications". Most interviewees were "White British" (n = 16; 89%), one was "Other White" and one was "Black Caribbean". They consumed between 28 and 103 units of alcohol per week, with a mean of 61 and median of 56 (where 1 UK unit = 8g ethanol). Ten interviewees had been DYD intervention participants (56%) and eight had been DYD control participants. Interviewee characteristics closely

resembled those of participants in the DYD trial (see Table 10). Most interviewees were interviewed in-person in London (n=10), two were interviewed in-person in York and six were interviewed over the telephone.

**Table 10. Participant characteristics - interview sample vs. sampling frame**

Participant characteristics	Interview sample (n=18)	DYD-RCT (n=7,935)
Female	10 (56%)	4,545 (57%)
Mean age (yrs)	43	38
University degree qualification or above (%)	11 (61%)	4,095 (52%)
White British	16 (89%)	6,635 (84%)
Mean past-week alcohol intake (UK units)	61	59
Randomised to DYD intervention (%)	10 (56%)	3,972 (50%)

### **The experience of the e-help seeker**

Analysis of the data identified clear themes that were apparent in the experience of the e-help seeker. These related to problem recognition and the type of help wanted, barriers to formal help seeking including stigma and gaps in services, and experience of resources accessed.

### **Problem recognition**

A range of motives led interviewees to search for help online, with most interviewees aware that their drinking was a problem. A few interviewees, however, were uncertain whether they had a problem with alcohol and wanted to know what constituted normal social drinking. In some cases, their search was driven by the public health message of sensible drinking. Factors adding to this uncertainty included peers drinking similar amounts without concern, or doctors advocating the health benefits of “a couple of glasses of red wine a day”. [Ppt.12 Male 67, 47 units/wk; DYD control]

"I was kind of at that point just kind of desperate to find something really, that would give me more information as to what is considered to be normal drinking, and what is considered to be very harmful drinking. Umm...and that's what I was looking for. And I think also around that time as well, a lot of my friends in [place] do tend to drink just how I drank, so...umm, there was a bit of, oh well...I drink sometimes less than some of my friends and how comes the alcohol isn't affecting them how it's affected me?" [Ppt.2 Female 25, 48 units/wk; DYD control]

"I don't really know how much I drink and I was sort of acutely aware that I probably drank more nights than I didn't drink, probably not that much but I never really had an idea. I'm aware that if I go out I normally drink more than other people which is maybe the infrequency I go out; it doesn't matter, but I'm just sort of aware of those things. So, sort of when I saw it [Down Your Drink] I think those two things sort of clicked together." [Ppt.15 Male 27, 28 units/wk; DYD intervention]

"There must be a lot of people that, like me, I'm curious as to A, why do they drink so much and B, is what they're drinking in such copious amounts doing any harm or not? And is that sound enough reason to cease." [Ppt.12 Male 67, 47 units/wk; DYD control]

Although concerned about their drinking, a few interviewees were not ready to admit they had a problem. They were afraid of what it would mean to do so as many viewed having an alcohol problem as synonymous with being an alcoholic. This led to some confusion, as the interviewees did not consider themselves alcoholics.

"I've always looked for what people consider too much to drink, whether, whether in conversations or... like with the doctor, or on there [DYD] or with the, you know... Ah, because, as I say, I, I think we do have this hope, ah, because you do not see

yourself as an alcoholic but you've come to the point where you realise that you can't do without it, so therefore you must be." [Ppt.11 Male 67, 87 units/wk; DYD intervention]

### **Type of help wanted**

Differences in need led to differences in the type of help required. Some interviewees wanted to determine whether the amount they were drinking was within safe limits and to compare their drinking with others. They wanted further information on what constituted harmful drinking, convincing evidence of the associated harms, and help to prevent a problem materialising. Most interviewees wanted help and advice on cutting down with what they believed was a problem. They wanted something to help them think about their drinking and reassurance that they were not alone. Not all participants were sure exactly what type of help they needed, or whether it existed.

"I was trying to spot and stop potential problems... I thought, no, it is creeping up a bit and, you know, there are a couple of times when we've been out when I've had too much, more than I'm comfortable with and let's nip it in the bud." [Ppt.8 Female 46, 72 units/wk; DYD intervention]

"I kind of wanted to feel that I wasn't alone, because at that stage I was kind of like, I know I have a drink issue, and I kind of just feel a bit alien, because no one else appears to be concerned with their drinking, but I'm very concerned about my drinking. And I kind of felt very alone with that, like maybe I was the only one in the world that had this problem." [Ppt.2 Female 25, 48 units/wk; DYD control]

"I didn't really know at that stage what I wanted, you know; I knew that I needed or wanted to do something that helped me think about my drinking." [Ppt.6 Female 60, 38 units/wk; DYD control]

### **Barriers to formal help seeking**

It was clear that the privacy provided by the Internet was important when searching for help with drinking. The stigma and embarrassment associated with seeking help for an alcohol problem was apparent in this sample of hazardous drinkers. For many, their drinking behaviour was seen as a very personal problem and they did not want to involve other people when looking for help to cut down. Difficulties talking about their drinking face-to-face, the embarrassment, admission of weakness / not coping and the fear of people finding out how much they drank meant a reluctance to seek help in-person from a doctor or alcohol worker. The quotation below is from an interviewee who had seen in their doctor's surgery and local community centre an advertisement for people concerned about their drinking and explains why they would not have attended.

"I think I'm not the only type of person that would sort of be like, I might bang into other people and be a bit embarrassed. I actually wouldn't acknowledge I was [seeking help], or what is it you say, you know, airing your dirty washing in public." [Ppt.9 Female 40, 47 units/wk; DYD control]

"It's all about being impersonal, frankly... [searching for help online] cause this is very, very difficult to come here and discuss this, actually. Umm...and it's very difficult to...uhh, cause basically what it comes down to is like admitting that you've got a kind of alcohol problem, umm...because...well first I was just thinking about this the way here; I mean first thing is this kind of...in my perception at least, this almost 'grey' area between umm...normal social drinking and being a smelly tramp

in the street. You know, if you've got a problem with drinking, then umm...then it doesn't really occur to me that there's a spectrum of stuff along there. Umm...and I suppose...umm...yeah, I mean it's kind of saying that you've got a problem with drink, seems like uhh...kind of admission of weakness of something I suppose. So it's much easier to just like, anonymously search on Google, than try and find something where you don't actually have to go and talk to your doctor, or whatever...umm...so yeah, that was my motivation, plus that fact I'm always on the computer." [Ppt.3 Male 44, 92 units/wk; DYD intervention]

Another barrier to accessing formal alcohol services was the perceived gap in service provision, with no apparent spectrum of services for people wanting to moderate rather than abstain from drinking. The first treatment option that came to mind after recognising the need for help was Alcoholics Anonymous (AA) (a form of collective mutual aid). It also appeared to be the only option available or known to many interviewees. This added to the stigma of help seeking as AA was perceived as catering for alcoholics. Only one interviewee had actually attended the meetings. The others felt the program was not appropriate for them, that their problem was not severe enough and that they did not identify with the types of people AA was targeted toward. Interviewees wanted help suited to their level of need, that did not interfere with their everyday lives and that was personal to them. There was also a concern that by attending a service geared toward the more dependent drinker, that this would trivialise their problem.

"The reason, I [didn't go to AA], I think probably the stigma that's attached to it. And it's not because, you know, I think I'm any better than anybody else, but I thought, I think I was probably concerned that they would do the same that that doctor had done to me, and say that I was actually okay, because there was alcoholics there. So in comparison with them I might have been drinking hardly anything, although to me, I know that it is too much. I was a little bit scared

because I sort of thought, you know, alcoholics, there are some people that'll drink really, really, an awful lot, and if I'm put alongside them I might actually think it's okay what I'm doing. So from that point of view, and then I thought, if they say to me not to drink at all. And I didn't want not to drink at all. I didn't want them to tell me not to drink, because I did want to drink, and I thought, you know, that's not what this is all about. So it just didn't seem to be the right thing. But it was the only place I knew where to go and get help." [Ppt.9 Female 40, 47 units/wk; DYD control]

"When I looked at things like Alcoholics Anonymous and I read it and I thought, well, I don't have that problem, I haven't had that problem, I haven't had that problem, and actually I don't want to give up completely and I don't want to go to a group." [Ppt.8 Female 46, 72 units/wk; DYD intervention]

"I do think, because it, well, again this is just a personal, sort of, thing that, AA is wonderful and that will help a lot of people I'm absolutely sure, but I am positive there is a place for a much more middle-ground which Down Your Drink seems to be, a more reassuring for, you know, people that haven't got the major, major, you know, life changing problems that it comes with, but want to do something." [Ppt.6 Female 60, 38 units/wk; DYD intervention]

### **Resources accessed**

Some interviewees searched for help both online and offline (i.e. in-person and via self-help books). Help was accessed before, during and after registration with the Down Your Drink website. Some interviewees used a variety of resources until they found something



that worked for them, whilst others used the DYD intervention or control website as a “one-stop shop” [Ppt.5 Male 44, 74 units/wk; DYD control]

## **Services accessed in-person**

### *Primary Care*

Although many interviewees did not feel comfortable talking to their doctors about their drinking, there were others who did broach the subject, all of whom reported a negative experience. It was felt that some doctors did not take the issue seriously, with one reported as saying “you’re not an alcoholic until you drink more than your doctor does” [Ppt.11 Male 67, 87 units/wk; DYD intervention]. Some interviewees were told they did not have a problem with alcohol, which gave them the ‘Okay’ to continue drinking at their current level and consequently delayed further help seeking.

“I remember sort of thinking perhaps when I signed up for my GP a few years ago and he asked me if I smoked, and I was like well kind of you know, on and off, and he sort of said, you know, have you thought about joining the NHS stop smoking thing, sort of duh duh duh, and I was like, I don’t really think, well you know, I was a bit more concerned about my drinking, and he said well you know, smoking’s worse, worse for you, and I was like oh right, well that’s not very helpful.” [Ppt.4 Female 30, 39 units/wk; DYD intervention]

“I mean, years and years ago I had gone to a doctor, and I wasn’t even drinking nearly as much as what I ended up drinking, but I was concerned about the way that I was drinking. And I confided in him. I was there about something else, and I said to him, you know, within a week I probably drink maybe three to four bottles of wine. And he said it was okay. And because of that, I know it sounds really stupid,

it gave me the okay to continue to do it.” [Ppt.9 Female 40, 47 units/wk; DYD control]

“I had said to people before that I was concerned about my drinking and it had been... one was to a doctor and he told me, oh you’re quite intelligent, I don’t think you’ll have a problem, and it’s like even then I knew it hadn’t got anything to do with intelligence at all, you know.” [Ppt.7 Female 44, 54 units/wk; DYD intervention]

Other interviewees were told to cut down with no help or advice on how to do so, with one doctor reported as saying “well, I can’t refer you to anyone...just don’t drink” [Ppt.2 Female 25, 48 units/wk; DYD control].

#### *Alcohol support / treatment services*

A few interviewees attended an in-person support service that involved meeting periodically with an alcohol worker. These services were identified opportunistically, e.g. from a poster in the doctor’s surgery, an advertisement in the Guardian newspaper, and working in close proximity to a treatment centre. The experience of attending such a service was generally a negative one. Positive aspects of one particular service were that it was client-led and there was no limit on the frequency of visits. The other services were criticised for the staff being too nice and not strict enough, being too preoccupied with the root cause of their drinking (which they felt was irrelevant), and for focussing on dependent drinkers. One participant did attend an alcohol treatment centre for detoxification, which included a course of benzodiazepines. They felt this treatment was too extreme and not suited to the severity of their problem, but there did not appear to be any alternatives to “inpatient treatments or outpatient treatments from [sic] extreme groups” [Ppt.14 Male 34, 62 units/wk; DYD control].

### **Self-help resources (offline)**

The self-help book by Allen Carr – “Easy Way To Control Alcohol”, was a popular resource. Many interviewees reported reading this book, whilst others had read his “Easy Way To Stop Smoking”. Allen Carr’s view, that it is easy to control (or abstain from) alcohol, was appreciated for being encouraging from the outset. These interviewees tended to abstain rather than moderate their drinking, which was the intention of the book. Failed attempts to successfully moderate their drinking led these interviewees to the conclusion that abstinence was probably the best option for them. A lack of support services for maintaining abstinence (other than AA) was also raised.

### **Resources accessed online**

Interviewees felt that most of the resources available over the Internet were abstinence-based programs tailored toward dependent drinkers. Many required a fee and were considered “commercialised” or “Americanised”, which did not appeal to this group of e-help seekers.

### *Forums*

Two interviewees accessed an online forum that was free to view. Neither participant contributed to the discussions but read about other people’s experiences of reducing their alcohol consumption. Reported strengths of the forum included refusal techniques and reference to self-help books (namely Allen Carr). There was some concern that forums could be detrimental to efforts to cut down on drinking if people were reporting their failure to do so. Interviewees were most interested in hearing success stories from people in situations that they could relate to.

“I ended up finding a site called Bright Eye counselling, which is an online counselling service for which they want you to pay, but umm...it’s got various

articles that are free to read and it's also got an online support forum. And although I didn't actually join the forum or anything, I read masses of what people were saying to each other there... and from Bright Eye, I was directed to a book, 'Allen Carr's easy way to control alcohol'...And I bought that book and I read it, and that was when I stopped...I mean it's all sort of happening much the same time though, because I stopped after the week when Down Your Drink had told me that I had 106 units, but at the same time I was reading Bright Eye and umm...and I read this book [Allen Carr], and it all sort of came together." [Ppt.1 Female 39, 58 units/wk; DYD intervention]

#### *Down Your Drink website*

The DYD website consisted of a screening test, trial invitation pages and then randomised access to either DYD intervention or control areas.

Some interviewees found the existence of the DYD website to be reassuring; it meant that they were not alone and there were routes out of their problem.

"I felt really quite desperate and scared and I think that... it didn't, the website didn't normalise it but I didn't feel so scared, I felt like there were routes out of where I was and I guess in terms of it being... you know, you say it is an online support then that is supportive, isn't it? That's what you need, you need to feel that you haven't completely messed everything up and there's no point in even trying to do anything about it." [Ppt.7 Female 44, 54 units/wk; DYD intervention]

"it's not just like telling people they've got a problem...this helps you through it [DYD website], and you know I think the fact that it's there makes you realise that

other people are, you know, going through it and that's quite reassuring" [Ppt.4  
Female 30, 39 units/wk; DYD intervention]

*Down Your Drink – trial assessment measures*

Certain features of the trial design, which tended not to be distinguished from the website as a whole, helped interviewees to determine the severity of their problem. These included feedback from the AUDIT-C screening test that 'you are at increased risk of harm from your drinking', recall of alcohol consumed over the past seven days and questions such as 'have you tended to drink on your own more than you use to?' from the Alcohol Problems Questionnaire (Williams & Drummond 1994). These features reportedly acted as a catalyst to change. They allowed interviewees to determine the severity of their problem in a safe and anonymous environment. This gave them the confidence to seek further help, with the website acting as the first step in a self-initiated stepped care approach. The website did not always prompt change, yet it was reported to "plant seeds" [Ppt.2 Female 25, 48 units/wk; DYD control] in people's minds. Email prompts to complete follow-up questionnaires were also a favourable aspect of the trial design. This contact from the site served as a welcome prompt to keep their drinking in check.

"What it did [DYD website] was it made me think, yes I do really need to address this and the thing about it being on the Internet was it was really safe and anonymous and everything and I could make a decision about whether I actually wanted to go and be face to face with someone, you know, which I did. So, you know, in terms of that it was quite a big part really of me sort of addressing things."  
[Ppt.7 Female 44, 54 units/wk; DYD intervention]

Most interviewees felt it was important to report their drinking honestly in the questionnaires otherwise they would only be kidding themselves. Self-reported veracity

was attributed to the anonymity provided by the Internet setting. Comparisons were drawn with the under-reporting of alcohol intake with a GP.

“I could have gone there every day and put in zero units, but I’m kidding who? Myself.” [Ppt.13 Male 45, 103 units/wk; DYD intervention]

“With the website, I think I told the truth. I mean I never tell the truth to the doctor but luckily I’m a very healthy, well, again, outwardly, a very healthy person so I don’t go to the doctor often so I just sort of skirt around how much are you drinking issues, which is usually part of it, you know, just a health questionnaire rather than anything else... So, and because of that anonymity and the fact that there was nothing about the website that made you feel judged, made it easier to just to be upfront with it, I think.” [Ppt.10 Female 51, 79 units/wk; DYD control]

“I lied slightly to your website but far less than I would do to my doctor. Much, much less than I would do to my wife!” [Ppt.3 Male 44, 92 units/wk; DYD intervention]

A few interviewees specifically mentioned the research team with regard to the veracity of their self-report data. Questionnaires were not completed truthfully as these interviewees were aware of what the researchers might think of their heavy drinking, or were embarrassed they had not cut down (this interviewee had received a telephone prompt for follow-up). Interestingly, those interviewees that under-reported their alcohol intake commented on how this provided the impetus to then change their drinking. In contrast, another interviewee felt they could be honest about their drinking as the researchers “don’t really care how many units I drink”. [Ppt.15 Male 27, 28 units/wk; DYD intervention]

“I was aware that there were researchers on the other side of the website who might be kind of looking at my randomised, anonymised data and thinking, ‘oh God

you piss head, what have you been doing this week?'. ” [Ppt.3 Male 44, 92 units/wk; DYD intervention]

“I got an email through that asked me how I was doing. And I lied... blatantly lied. And I was embarrassed. And I think because it is online, you're more likely to be honest. I actually think I got a phone call, and it was a person I spoke to [telephone follow-up – see Chapter 3]... It was because I spoke to somebody, I was too embarrassed. Because I think I felt as if they were trying, like really hard to have somebody successful, and so I didn't want to let them down. And that sounds really stupid because that's not a true indication of how your thing is. But I was just so embarrassed.” [Ppt.9 Female 40, 47 units/wk; DYD control]

Although many of the interviewees said they had reported their drinking honestly, some delayed completing the questionnaires until they had cut down. Others, who had changed their drinking and were now abstinent, did not complete the questionnaires, as they were no longer relevant to them.

“I remember when that happened the first time [received email prompt] as well and I thought, oh I'll put it off till next week and then I put in some more flattering figures... It's not very good behaviour because if you...well it probably is if you actually do make yourself drink less in order to fill the survey but, if you carry on with your normal behaviour and then you got even worse figures... 'oh that's not better so maybe wait another week'.” [Ppt.3 Male 44, 92 units/wk; DYD intervention]

“So probably for me now, I wouldn't fill out the surveys as much because I'm now a T-totaller. Umm...but if I was still drinking, I think I would actually still be filling them

out. If I was still in the situation I'd still be filling them out." [Ppt.2 Female 25, 48 units/wk; DYD control]

### *Down Your Drink - intervention*

For those interviewees who had received access to the intervention arm of the trial, the most commonly reported tool was the Drinking Episode Diary (Linke et al. 2008). The diary helped interviewees to ascertain how much they were drinking and the shock of the feedback provided the impetus needed to cut down. The diary was also used to monitor drinking over time by prompting people to keep an eye on their consumption.

Documenting thoughts and feelings surrounding different drinking episodes helped a few interviewees to identify reasons for drinking and to consider ways of reducing it.

"I would say probably for me the most useful thing [Drinking Episode Diary]. I only used it for a short while and then every now and again when I, you know, think, oh, perhaps it's creeping up again, use it again just to, you know, it keeps you from the wrong track and things." [Ppt.8 Female 46, 72 units/wk; DYD intervention]

"The thing is, it gives you a shock when you add up the total units. And it's no good... it's no good being dishonest with yourself. If you're going to be lying about it, why do it? So, I wrote down everything truthfully, and when you see something like 60 units, you know when you think, Jesus, I've to cut back a bit. It just gives you a wake-up call." [Ppt.13 Male 45, 103 units/wk; DYD intervention]

"I think the first week I actually did it, when it came up with, not so much the money but the calorie intake, and I thought 'Christ, I go the gym 3 days a week' you know, I managed to burn off a total of like 1000 calories a time if I'm lucky, or less. And the amount that I'm drinking was twice or 3 times that, and just thought 'no wonder



I can't lose weight'. And it's mad, that was another kind of useful motivator for me."

[Ppt.3 Male 44, 92 units/wk; DYD intervention]

Interviewees reported other helpful tools on the website, including the 'alcohol and relationships' feature that identified drinking partners, the blood alcohol concentration calculator, methods for 'surfing' cravings, and acceptance of lapses. Interviewees also reported finding tips for cutting down useful, such as swapping alcoholic drinks for non-alcoholic drinks, choosing low-alcohol alternatives, and changing the type of alcohol they consume (i.e. wine rather than gin). Interviewees also liked being taught how to calculate the number of units in drinks and the importance of percentage of Alcohol By Volume (%ABV).

"something again made me sit up and really wake up to the fact that I was drinking too much, was there was some kind of calculation or explanation of how...umm, how fit you are to drive...you know over the years I would say oh two glasses of wine, that's absolutely fine, and I can drive after that, and that, I thought that was brilliant, umm...because it really made me realise that, you know, not only are not fit to drive that night but quite often you're not fit to drive the next morning, and I was pretty shocked by that actually... Oh I tell you what the other interesting statistic was, being able to work out how many units there was in something from the percentage, the volume, the percentage and the amount. I never had that taught to me before... Because particularly with wine having got so much stronger, you know, you used to think that a small glass of wine is 1 unit. You know, it shows it's much more. I found that really interesting." [Ppt.1 Female 39, 58 units/wk; DYD intervention]

"I appreciated... and it was unknown to me, the blood alcohol and the driving thing, you know, those indicators there and the unit converting the units, the blood

alcohol. I can't remember there's about two or three, aren't there that you can... But I found the one on the drinking and the limit and everything else, they were good. Just to sort of tell you how it affected me is that when I realised it, I saw those figures, it made me then, during the week, on the nights I was drinking at home, consciously make sure I kept to the limit I said I was going to, and consciously finish drinking earlier." [Ppt.8 Female 46, 72 units/wk; DYD intervention]

A few interviewees reported similarities between the DYD intervention website and other behaviour change websites they had used to lose weight or stop smoking.

"When I started looking at the way the Down Your Drink website was phrased and the way it was working, and it was supportive as opposed to being dictatorial. I thought, oh, this reminds me of Weight Watchers. And, you know, the drinking diary. Oh, that reminds me of my food diary... the support and the help and the practical tips you get and the assessing it all different ways not just the practical methods of, you know, don't drink now, or learn to drink more slowly, or count, you know, just keeping a note and a record. But also addressing the, sort of, reasons behind sometimes why you do it.... certain circumstances and how to, sort of, change your behaviour slightly so that you can still eat but in moderation and the right things and enjoy it." [Ppt.8 Female 46, 72 units/wk; DYD intervention]

Many interviewees valued the convenience, flexibility and anonymity of the DYD website, with one interviewee saying it was the most obvious source of help as they were always on their computer. DYD's affiliation with a university was thought to give it credibility over other websites. Many interviewees liked the non-judgemental tone of the site, whilst others would have preferred a starker approach. A few improvements to the site's usability were suggested, such as improving the ease in which units could be entered into

the Drinking Episode Diary. Whilst some interviewees felt it was “good for dipping back for something that wasn’t particularly relevant at the time” [Ppt.8 Female 46, 72 units/wk; DYD intervention], others felt reminders and reasons to revisit the site were necessary. A number of interviewees suggested the addition of a forum, but they also felt this could backfire if people were seen as failing. Success stories were another idea thought to be beneficial: “not necessarily somebody who’s really down and out or whatever, but here’s somebody who has taken control of their drinking.” [Ppt.1 Female 39, 58 units/wk; DYD intervention]

“My experience compared with, um, the counsellor that you would go and see... I’m getting on much better with the website version than, than the other. Some of that maybe idleness, um, because there’s obviously less effort to go on to website than it is to go out...But at the same time it’s also, the fact that it’s there when you need it and the counsellor isn’t... well you don’t drive and use petrol, you don’t get wet [laughter]... it’s, it’s very convenient.” [Ppt.11 Male 67, 87 units/wk; DYD intervention]

“It was one of the first [website] that didn’t look like it was a commercial thing, umm.... It had an air of credibility as it had an @ac.uk address or something. It was a bit more umm...a bit more credible than, you know, a big garish ‘I can help change your life’ type thing... And it was positive, umm...and it’s very non-judgmental, I mean the language throughout the website, I thought, was very well pitched, to be reassuring to somebody coming and signing up. That was the impression I got anyway.” [Ppt.3 Male 44, 92 units/wk; DYD intervention]

“I thought the questions and comments that came up were far too reassuring, if that makes any sense?...it was full of “don’t worry, you won’t, you may only just be this...” or, I mean, not those phrases, but there are sort of comments and phrases

that are meant to reassure you throughout, and I thought that was, for me, a huge mistake. A bit more starkness [was needed], a bit more scary stuff, a bit more starkness, a bit more, “oh, gosh, you’re drinking five glasses of wine a night”, or whatever, it wasn’t every night, but say I was drinking that five a night, “that is equal to so many units, you know, you can stop, but you know what that can do...”; that would have been a lot better for me.” [Ppt.6 Female 60, 38 units/wk; DYD intervention]

## ***Discussion***

The findings from these interviews provide an illuminating insight into a previously unstudied population of people searching the Internet for help to reduce their drinking, their experience of using an Internet-based intervention and taking part in an online trial.

Most of the interviewees in this study were searching online for help to reduce their drinking, having recognised a problem that needed addressing. This finding is congruent with previous research in dependent drinkers, where problem recognition is an established antecedent to seeking treatment (Finney & Moos 1995; Jordan & Oei 1989; Orford et al. 2006b; Sobell et al. 1991). There were, however, a few interviewees who were less convinced that their drinking needed changing. Their search for help was driven by public health messages on sensible drinking, but was confused by the advocated health benefits of “a couple of glasses of red wine” and by peers drinking similar amounts. Unlike cigarette smoking, not all alcohol consumption is considered harmful. For those drinking small amounts of alcohol on a regular basis there is even thought to be some health gain, particularly for ischemic cardiovascular outcomes and diabetes (Rehm et al. 2009). What is perhaps less known among the general public is that the suggested health benefits apply only to older men (over 40 years) and postmenopausal women drinking within safe

limits (Department of Health 2009; Royal Colleges 1995); while the risk of cancer increases with any amount of alcohol consumption (Department of Health 2009; Schutze et al. 2011). In addition to the confusing public health message is the fact that alcohol consumption is ingrained in UK culture (British Medical Association 2008). This acceptance of alcohol misuse among peers and society further complicates the sensible drinking message. These findings point to the need for clearer public health messages.

Interviewees expressed a commonality of need for help to moderate their drinking, yet the type of help they required was varied, reflecting to some extent the degrees of problem recognition. One explanation for this variation in problem recognition and treatment need was the privacy of the online setting in mitigating some of the barriers to seeking help, allowing people to access help at an earlier stage with their problem. Many of the interviewees in this study attributed their online search for help to the privacy and anonymity provided by the Internet – a widely stated advantage of Internet-based interventions. In line with previous research in dependent drinkers, the stigma and embarrassment associated with help seeking for an alcohol problem prevented many of the interviewees from searching for help in-person (Cunningham et al. 1993; Finney & Moos 1995; Grant 1997; Hingson et al. 1982; Jordan & Oei 1989; Sobell et al. 1991; Sobell et al. 2000; Thom 1986). Internet-based interventions are therefore anticipated to benefit a large group of hazardous and harmful drinkers whose needs are otherwise unmet.

There was an almost unanimously perceived lack of services for non-dependent drinkers wanting to moderate their drinking, providing another barrier to seeking help in-person. Alcoholics Anonymous was often the first and only service that came to mind, adding to the stigma surrounding help seeking. AA was not accessed by the interviewees (except for one) as it was unsuited to their level of need. Brief interventions are advocated for

hazardous drinkers not seeking help for an alcohol problem (i.e. non-help seekers). Unlike AA, which is widely publicised, brief interventions are not. This may be because of the non-help seeking individuals they target, or because brief interventions are not routinely offered in primary care or by other services. There is a limited budget for alcohol services in England (0.1% of Primary Care Trust budget), most of which is spent on specialist treatment for dependent drinkers (National Audit Office 2008). The popularity of the DYD website (reported in Chapter 3) and the user's experiences reported in this chapter indicate there is considerable unmet need among people whose drinking does not warrant specialist treatment, but does require some degree of advice and support. The needs of these e-help seekers are currently overlooked; thus, these findings provide important implications for future service provision in this country.

Another prominent theme identified in this study was the negative experience of in-person services, particularly in primary care. Interviewees perceived their doctors as either not recognising their drinking as a problem or suggesting they cut down without any offer of help. Previous qualitative research has found that for some GPs drinking at hazardous or harmful levels themselves, a patient's drinking would need to exceed their own for it to be considered a problem (Kaner et al. 2006). Other qualitative research with GPs reported there to be insufficient services to refer patients onto, with specialist services catering for illicit drug users rather than problem drinkers (Rapley et al. 2006). It should, however, be noted that those people with positive experiences of primary care may not have needed to seek help online and therefore would not have been captured by this study. Nevertheless, the barriers to delivering brief interventions in primary care are numerous, with hazardous drinkers rarely identified (Cheeta et al. 2008). Whilst research continues to focus on how best to overcome these barriers (Nilsen 2010), the existence of a range of online services suited to hazardous drinkers would provide a valuable addition to the current provision of

services and provide GPs with a service they can refer onto, with no waiting lists or funding restraints.

These qualitative interviews also helped illuminate the findings of the DYD trial, where both experimental groups were found to reduce their alcohol intake. Interviewees in both DYD conditions reported on the benefits of trial assessment and follow-up prompts. It was suggested in Chapter 3 that both intervention and control areas of the site may have been equally effective. This possible explanation for the trial results was not supported by this study, where interviewees in the intervention group talked at length about components of the site that had been of help to them, unlike interviewees in the control group. This was a group of hazardous and harmful drinkers motivated to search online for help or further information on their drinking. This motivation was also demonstrated by the range of resources accessed by some interviewees in both groups of the trial. Resources were accessed both online and offline, either before, alongside or after access to DYD, and in some cases DYD acted as the first step in a self-initiated stepped care approach. The findings from this qualitative study are consistent with those of previous qualitative research with dependent drinkers in the UKATT trial, which suggests that the treatment system is complex, consisting of the intervention itself, trial assessment, other resources accessed, and self-directed change (Orford et al. 2009).

The finding that the trial assessment procedures were not distinguished from the DYD website itself may have important implications for the high rates of attrition found in the DYD RCT, and other online trials. Follow-up questionnaires were not completed in some instances where interviewees had stopped drinking and therefore considered them irrelevant. The use of self-reported alcohol consumption data to assess the effectiveness of interventions was similar to the process of self-monitoring, a known behaviour change technique (Abraham & Michie 2008) and was a common component of Internet-based

interventions for reducing alcohol intake (see Chapter 2). It may not be possible to separate the impact of assessment measures on drinking behaviour, however, future studies could make greater efforts to distinguish between these activities, emphasising the importance of the data to the success of the trial. The fact that interviewees did not distinguish between trial assessment measures and the DYD website provided some explanation for the differential follow-up observed in the DYD RCT (see Chapter 3), where a greater response rate was found among DYD control participants. Participants in the control group welcomed the assessment measures as an opportunity to reflect on their drinking, with the DYD control website only providing basic information on alcohol-related harm. Process evaluations, in the form of qualitative interviews, may help illuminate further reasons for attrition in online trials and help researchers address this major methodological challenge and potential source of bias.

This was one of the first qualitative studies in this field to explore the experiences of a novel sample of people searching online for help to reduce their drinking and consenting to participate in an online trial. An advantage of taking an inductive approach to analysis is that the presentation of findings was driven by the issues that were important to this participant group. The characteristics of the interviewees in this study mirrored those of the wider DYD participant population, and through reaching saturation, the findings are likely to transfer to a slightly broader population of people seeking help online to reduce their drinking. However, it is important to acknowledge the reasons why the views of this sample of interviewees may not represent those of the wider population. The interviewees in this study responded to an advertised opportunity to provide feedback on their experience of using the DYD website and participating in the trial. It is likely that many potential interviewees did not want to jeopardise their anonymity by talking to a member of the research team. The discussion of alcohol problems is a sensitive topic, which clearly emerged during the interviews, with one interviewee admitting it was extremely hard for



them to attend as nobody knew they were seeking help. Some interviewees reported participating out of gratitude to the DYD team, a motivation which is likely to lead to bias in favour of the DYD website. Finally, it is important to remember that the information obtained from these interviews was from the participant's personal experience and therefore a subjective reality.

## ***Conclusion***

This study provides a unique insight into a group of hazardous and harmful drinkers who value the convenience, flexibility and anonymity of the Internet when seeking help or information on their drinking. These were people who varied in problem recognition and displayed a range of need that is currently unmet by existing services. The Internet provided a gateway to resources both on- and offline. Through searching the Internet for help to reduce drinking, people are likely to encounter a range of resources that they may or may not utilise. In a motivated participant group, this suggests that people are accessing a number of different resources until they find something of help to them.

## Chapter 7: Discussion

Alcohol is among the leading causes of preventable mortality and morbidity in Europe (Rehm et al. 2009). Alcohol-related harm also extends beyond the individual to affect other people, society and the economy, making it the most harmful drug in the UK (Nutt et al. 2010). Hazardous drinkers cause the majority of this harm by constituting the largest group of alcohol misusers (The NHS Information Centre 2009). Effective interventions for reducing alcohol intake in hazardous drinkers exist, yet there are numerous barriers to their delivery in-person (Drummond et al. 2005; Hutchings 2006; Johnson et al. 2011; McAvoy et al. 2001; Rapley et al. 2006; Wutzke et al. 1998) resulting in a gap between need and access to care, the extent of which is yet to be determined (Drummond et al. 2011). This thesis aimed to explore the use of the Internet in delivering and evaluating interventions for reducing alcohol intake with a view to widening the availability of services for hazardous drinkers. It addressed this aim through a series of empirical studies, using a range of research methodologies suited to each research question. Each study mirrored the aims and objectives of the thesis and addressed a question of importance to the development of this emerging field. An in-depth discussion of each empirical study contributing to this thesis was provided in the previous chapters, which included consideration of the previous literature, strengths and limitations of the study and implications for future research. This chapter begins by recapping the findings of each empirical study, discussing further strengths and weaknesses and considering how each study might inform and sometimes challenge others. It then explores some of the broader issues of interest to this field, including the unique population of e-help seekers identified by this thesis, potential barriers to implementing Internet-based interventions, reaching different populations in different settings, and the future development of Internet-based interventions.

## ***Computer-based interventions for reducing alcohol intake***

This thesis began its empirical exploration of the Internet for delivering alcohol misuse interventions with a systematic review of stand-alone computer-based interventions aimed at reducing alcohol intake in adults (Chapter 2). Computer-based interventions were found to be effective at reducing total weekly consumption and frequency of binge drinking in adults when compared with minimally active comparator groups. These findings are supported by several recently published reviews (Carey et al. 2009; Elliott et al. 2008; Rooke et al. 2010), yet these were tentative conclusions in light of the methodological weaknesses of the studies, such as the use of unsuitable measures of central tendency, small sample sizes, short-term follow-up, and insufficient information to judge potential sources of bias. Nevertheless, it may have been premature to generalise the conclusions to all adults given the small number of studies in non-student populations. Only three studies in adults from the general population and one study in emergency department attendees were included in these analyses. Several studies have been published since the completion of this review, yet the majority remain in student samples (Bewick et al. 2010; Hustad et al. 2010; Kypri et al. 2009; Neighbors et al. 2009; Walters et al. 2009). Whilst hazardous drinking is highly prevalent among university students (Bewick et al. 2008a; Gill 2002; Wechsler et al. 1994), they represent a small proportion of adults in the general population known to be drinking at these levels. There is a clear need for further research on the effectiveness of computer-based interventions in non-student samples. This will permit future reviews to perform separate meta-analyses for different non-student population groups, which will reliably inform policy makers and service providers.

The three studies in adults from the general population included in the systematic review found the computer-based intervention to be more effective than the minimally active comparator group, and demonstrated a more pronounced effect than in the student populations. In contrast, the DYD trial found no difference between its intervention and

minimally active comparator arm in a non-student sample. The findings of the trial therefore challenge those of the review that computer-based interventions are effective in adults. Nevertheless, a key difference between the study populations that prevents comparison (or future pooling of results) is that the participants in the DYD trial were seeking help with their drinking, unlike the general population samples in the systematic review. As mentioned in Chapter 1, treatment seekers are more likely to benefit from an intervention than non-treatment seekers (Apodaca & Miller 2003), with higher levels of motivation and readiness to change their drinking (Heather 1995). This motivation was demonstrated in Chapter 6 by the range of resources accessed by some interviewees in both arms of the trial, including in-person services, online resources, and self-help books. Resources were accessed both online and offline, either before, alongside or after access to DYD, and in some cases DYD acted as the first step in a self-initiated stepped care approach. This finding is consistent with that of previous qualitative research with dependent drinkers, suggesting that the treatment system is complex, consisting of the intervention itself, trial assessment, other resources accessed, and self-directed change (Orford et al. 2009).

The systematic review included studies of computer-based interventions aimed at reducing alcohol consumption, where alcohol consumption was measured over any time period. Increased alcohol intake is a proximal measure of harm, i.e. a reduction in alcohol intake leads to a reduction in the risk of harm. Harm is not always experienced by hazardous drinkers and is experienced in many different ways in harmful drinkers, therefore making it difficult to measure. Whilst the review was restricted to measures of consumption, there is no internationally agreed 'gold standard', as different outcomes reflect different patterns of drinking. As such, alcohol intake is assessed by different measures, in different formats, to calculate a variety of outcomes. To allow for the pooling of findings in meta-analyses the review selected two drinking outcomes thought to increase the likelihood of alcohol-

related harm (i.e. grams of alcohol consumed per week and frequency of binge drinking episodes per week). The use of mean differences provides a meaningful interpretation of the pooled data, which is particularly important if research is to inform policy. However, whilst the majority of studies in the review included some measure of total consumption, there were a few studies that did not and were therefore not included in the analyses. An alternative approach would have been to combine the findings of the studies as standardised mean differences, where the results of studies are standardised to a common scale. Whilst this allows for the inclusion of more of the data, findings are ambiguously interpreted as small, moderate or large effect sizes. In the absence of standard outcomes for different patterns of drinking, study authors will continue to use different drinking outcomes and reviewers will continue to make a trade-off between mean and standardised mean differences.

### ***An online measure of past-week alcohol consumption***

The use of the Internet for evaluating Internet-based interventions was considered in the context of the DYD RCT. This online trial demonstrated several methodological advantages of the Internet setting, including the ease of recruitment and data collection. However, it also faced a number of methodological challenges, one being that an outcome measure may not retain its psychometric properties when transferred online. Chapter 4 reported on the creation of an online measure of past-week alcohol intake (the TOT-AL) for use in determining the primary outcome in the DYD trial. The TOT-AL was found to be reliable and comparable with the in-person approach to eliciting alcohol intake. These findings were thought to generalise to a population with universal access to the Internet and where completion of the tool takes place in an anonymous setting; thus supporting the use of the TOT-AL in the DYD RCT. It must be noted that these conclusions were based on a sample restricted to students. As mentioned in Chapter 2, hazardous drinking is

common among university students (Bewick et al. 2008a; Gill 2002; Wechsler et al. 1994), thus providing a suitable sample for investigating the reliability and comparability of an online measure of alcohol intake for use in a trial of hazardous drinkers. However, when later compared with the sample characteristics of participants recruited to the DYD trial, participants in the TOT-AL studies were younger (average age 24 years compared with 38 years) and consumed around half the amount of alcohol (22 units per week compared with 46 units). This difference in consumption is particularly important as greater discrepancies were observed between the TOT-AL and the interview scores, and repeated completions of the TOT-AL, among the heavier drinkers. This challenges whether the findings of these studies would indeed generalise to the heavier drinking DYD population. Previous studies have observed this discrepancy between measures among heavier drinkers, which has been explained by impaired memory due to excessive drinking or heavier drinkers having more drinks to recall, thus creating a trickier task (Babor et al. 2000). Time and resource constraints prevented replication of this study with a heavier drinking population similar to that in the DYD trial, with this a worthy direction for future research.

The DYD trial needed an online measure of alcohol consumption to detect differences between experimental groups and change in consumption over time. As such, a measure of actual consumption over the past week was selected to optimise ease and accuracy of recall. Mean weekly alcohol intake was also chosen as the primary outcome for the systematic review, in-line with a recent Cochrane review of brief interventions in primary care (Kaner et al. 2007). Whilst studies that reported any measure of alcohol intake over any time period were eligible for inclusion in the review, most studies reported the quantity of alcohol as actual or average drinks or units consumed per week. In selecting the length of recall period for an actual consumption measure, a trade-off is made between accuracy of recall and typicality of drinking behaviour. One of the limitations of actual recall over the past week is that the typicality of reported alcohol consumption is unknown. Another

approach to measuring alcohol intake that does consider the typicality of drinking behaviour is the quantity / frequency index, the original version of which includes questions on the average amount of alcohol consumed (quantity) and the average number of days when alcohol is consumed (frequency) in a given time period (Straus & Bacon 1953). This approach is often used in screening tests as it can be completed with relative speed, however, it has been found to result in lower estimations of consumption compared with actual recall (Dawson 1998; Del Boca & Darkes 2003; Lemmens et al. 1992; Rehm 1998; Russell et al. 1991; Shakeshaft et al. 1999). Although the primary outcome in the DYD trial was based on the quantity of alcohol consumed, the TOT-AL also has the capacity to calculate a range of commonly measured drinking outcomes that reflect different patterns of alcohol intake, including the quantity, frequency and intensity of drinking. Whilst different drinking outcomes reflect different patterns of drinking, it would be of benefit to the field to select a range of standard outcomes and measures that are advocated for all evaluations of brief interventions to allow direct comparison of findings and the pooling of mean differences in meta-analyses.

### ***Incentives for improving follow-up in an online trial***

One of the advantages of online trials is that they may render some conventional sources of bias obsolete (discussed in Chapter 2). This was the experience of the DYD trial where sequence generation and randomisation occurred over the Internet in an automated process, thus concealing allocation to experimental groups. In addition, blinding of therapists and outcome assessors was not applicable when delivering and evaluating the intervention over the Internet. However, one of the biggest methodological challenges and potential sources of bias facing online trials is loss to follow-up. Like many online trials, the DYD RCT suffered from high rates of attrition. In an effort to improve follow-up, the impact of incentives was investigated in two of the first studies in an online trial (Chapter

5). The findings from these studies demonstrated that the offer of low value incentives (i.e. £5 Amazon voucher, £5 charity donation or £250 prize draw) did not improve follow-up, whereas a higher value incentive (i.e. £10 Amazon voucher) increased follow-up rates by 9%. This is an important finding as many trials offer incentives without knowledge of their impact, and where online trials have the capacity to recruit large numbers of participants there are substantial financial implications. Unfortunately the findings in study 1 are inconclusive due to its limited sample size and the higher than expected follow-up rates in the control arm. The survey literature suggests that varying the value of non-monetary incentives does not influence response to postal and electronic questionnaires, however this finding is based on low value comparisons (e.g. US\$1 vs. US\$2) (Edwards et al. 2009) and may not transfer to the use of incentives for improving retention in trials. Further research should aim to determine the lowest value of incentive that is effective at improving response. A three arm trial comparing no offer of incentive, with a £5 and £10 Amazon voucher is needed before any definitive conclusions can be made about the impact of lower value incentives. In the context of the DYD online trial, where follow-up rates were low and funding was available to offer incentives, a 9% increase in response was thought to be worth the expense. However, it is important to note that increased response rates do not necessarily reduce bias and therefore efforts are needed to investigate how incentives can be used to reduce non-response bias in addition to improving response rates.

Chapter 5 considers the ethics of incentivising participants to complete follow-up measures in the DYD trial, however, the use of incentives for participation in the TOT-AL studies in Chapter 4 and the qualitative interviews in Chapter 6 has not been discussed. The reliability and comparability studies in Chapter 4 recruited UCL students via email, offering a £10 cash incentive for participation. UCL students receive several email invitations a week to participate in research, and as such, most offer incentives in-light of the high



competition. These are often student projects and therefore the choice of incentive is likely to be driven by the limited budget, such as a prize draw for a book token. As discussed in Chapter 5 in relation to the participants in the incentive studies, participants in the TOT-AL studies were not coerced into taking part and accepting the incentive, nor did the use of incentives provide undue inducement as there were no risks involved in these studies. There was, in fact, a possibility that participation in the studies may be beneficial due to reactivity of assessment. Detailed information on the aim of the study, the procedure, and the advantages and disadvantages of taking part was provided before obtaining informed consent. The use of incentives for recruiting to the qualitative interviews in Chapter 6 is an important consideration as it may have influenced the type of people agreeing to participate, i.e. people of lower socioeconomic status. Of the 7,935 participants enrolled in the DYD trial, 18 agreed to be interviewed on their experience of searching for help online, using an Internet-based intervention and taking part in an online trial. Although there were no data on the socioeconomic status of these participants, interviewees all had access to the Internet (determined by self-recruiting to the DYD trial) and half had a university degree, thus suggesting that a £25 incentive would not provide undue inducement. The sensitive nature of this interview topic may have overridden any impact of the incentive on encouraging participation. Anonymity was particularly important to these participants, with one interviewee admitting it was extremely hard for them to attend as nobody knew they were seeking help with their drinking. Some interviewees reported participating out of gratitude to the DYD team for providing the website, and many wished to forfeit their incentive – the findings of the qualitative study are interpreted with this motivation in mind. It is important to consider the impact that incentives may have when recruiting for qualitative studies where no such motivation exists.

### ***Experience of taking part in an online trial***

The final empirical contribution to this thesis was a qualitative study of DYD participants' experiences of seeking help online, using an Internet-based intervention and taking part in an online trial (Chapter 6). In mitigating some of the barriers to seeking help in-person, the Internet attracted a population with varied needs, from those wanting to determine their level of alcohol intake to those wanting to address a recognised problem. The needs of these hazardous drinkers were currently unmet by existing services available both online and in-person, where services were perceived as catering for dependent drinkers. DYD participants were found to benefit from a number of aspects of the trial and intervention, in addition to in-person services and self-help resources, thus indicating that a 'one size fits all' approach may not reflect differences in individual need and preference. This is a novel finding that should shape the priority of research in this field, where the development of future services should be informed by the varied need and preferences for services among hazardous and harmful drinkers in the general population.

An important aspect of qualitative research is to consider the interviewer's knowledge, beliefs, values and the context in which the data were collected, and the influence this may have on the interpretation of the data; a process known as reflexivity. The interviewer (ZK) in this qualitative study was the lead researcher in the other three empirical studies included in this thesis, and the research fellow on the DYD trial. Qualitative research is a subjective process and it is therefore possible that the interviews were conducted and analysed in a way that was favourable to the DYD website and Internet-based interventions more generally. Attempts were made to minimise this influence. Interpretations of the data were discussed with two experienced qualitative researchers, one of which was not a member of the DYD team and thus provided the fresh perspective needed to identify any influence the interviewer may have imposed on data collection and analysis. In using an inductive approach to analysis, where themes were directly linked to

the data, the findings were driven by the issues that were important to this participant group and not those imposed on them by the interviewer. Attention was given to disconfirming evidence, where new information does not fit with current themes. Not all of the interviewees spoke favourably about the DYD intervention website, for example, a few did not like the non-judgemental tone, wishing for a starker approach, whilst others reported problems with navigation. It is possible that the interviewer's role as research fellow on the DYD trial may have limited negative feedback from the interviewees by enhancing social desirability bias. This may have been further exacerbated by performing the interviews within a university setting.

The interviews conducted in this study discussed people's experience of seeking help with their drinking; a sensitive topic with a sample of people who valued their anonymity. Although the characteristics of the interview sample mirrored those of the wider DYD trial, these were people who were prepared to break their anonymity and discuss their experience with a researcher from the DYD team either in-person or over the telephone. Some interviewees reported participating out of gratitude to the DYD team and this motive should be borne in mind when interpreting the findings. The sensitive nature of these interviews may explain the small number of people volunteering to participate in this study. In hindsight, alternative means of communicating with interviewees that protected their anonymity could have been made available, such as Skype. This form of online communication would have been particularly suited to this group of competent Internet users. An anonymous online survey of users' experiences may have attracted a broader range of participant views, yet it would not have achieved the same depth and insight into the issues important to this sample of DYD participants. Another explanation for the small number of volunteers for this qualitative study may have been the method of recruitment. Participants were largely recruited via the Down Your Drink study newsletter, which was circulated by email and therefore would not have been received by those participants who

had changed their email addresses since registering for the trial. A proportion of emails containing the newsletter were likely to have been caught by spam filters and were therefore undelivered. It is also likely that some people will have deleted the email before reading it, or missed the invitation to take part in the qualitative study contained within the newsletter. This is a problem with online studies that rely on email alone to communicate with participants; a disadvantage also experienced in the incentive studies. Future studies using email as a method of recruitment or retention should consider ways of overcoming spam filters and creating attention grabbing email subject headers.

### ***Unique population of e-help seekers***

This thesis has explored the experiences of a unique group of hazardous and harmful drinkers seeking help with their drinking online. One of the defining characteristics of hazardous drinkers is that they do not seek help with their drinking, thus making the e-help seekers in the DYD trial a previously unstudied population. Unlike the non-help seeking samples included in the systematic review (Chapter 2), DYD participants demonstrated some motivation to change their drinking by the way in which they self-recruited to the trial (i.e. in order to access help or information on reducing their drinking). Yet, despite seeking help with their drinking, DYD participants also differed from conventional help or treatment seekers by exhibiting low levels of dependence and fewer alcohol-related problems (Chapter 3). The DYD trial attracted a larger proportion of women than previous trials of non-treatment seekers (57% vs. 30%) (Kaner et al. 2007) and treatment seekers (57% vs. 26%) (UKATT Research Team 2005b). This more equal representation of men and women is encouraging, with women generally under-represented in alcohol research. The trial also recruited a larger proportion of participants educated to degree level than a previous trial of treatment seekers (52% vs. 10%) (UKATT Research Team 2005b). Not surprisingly, these characteristics reflect the demographics of people using the Internet,

where women have been found to search for health information more often than men (73% vs 63% respectively) (Dutton et al. 2009). The Internet is also more frequently used by people with a higher (university) education (93%) than those with a basic secondary education (49%) (Dutton et al. 2009).

The DYD intervention website was developed as a stand-alone Internet-based intervention, based on the principles of motivational interviewing, behavioural self-control, CBT and relapse prevention. This extended brief intervention is suited to those people who need more than screening and brief advice to cut down on their drinking, in line with the advocated stepped care approach (DH / National Treatment Agency for Substance Misuse 2006; NICE public health guidance 24 2010). With an average score of 19 on the AUDIT and 7 on the APQ, DYD intervention was reaching a population in need of an extended brief intervention. Nevertheless, attracting a potentially vulnerable group of people, with several alcohol-related problems, to a stand-alone Internet-based intervention without any therapeutic contact does raise ethical concerns. Previous studies of stand-alone computer-based interventions have included non-help seeking samples who were consequently a less vulnerable group with fewer alcohol-related problems (Chapter 2). The alcohol-related problems experienced by this e-help seeking population were identified by the trial assessment measures, but were not followed up in the programme. Participants were advised to contact their GP immediately if experiencing symptoms of withdrawal. It could be argued that there was a clinical obligation to intervene as the population attracted to the DYD website were experiencing greater problems than anticipated from a sample of hazardous drinkers. However, despite the problems experienced by these participants they had low to moderate levels of dependence and were largely not seeking specialist alcohol treatment (see Chapter 6). The convenience and anonymity of the Internet allowed participants to access help or information without the stigma associated with seeking help in-person. Had participants known that a clinician

may intervene and that their anonymity would be breached, they may not have chosen to use the site. Given that this was a previously under-served group of hazardous and harmful drinkers, who may otherwise not access help with their drinking, it is important that the anonymity of this service is maintained.

Users of DYD may also be vulnerable in that they suffer from comorbidities. It is now known, through secondary analysis of the DYD trial data, that over half of participants reported problems with depression and anxiety (57%), which is considerably higher than in the general population (21%) (Essex et al. 2012). These are common comorbidities associated with alcohol misuse, and for harmful and dependent drinkers it is recommended that their drinking is tackled prior to treatment for anxiety and depression as symptoms of the latter may improve (NICE Pathways 2011). Future development of the DYD website should consider adding a section on the symptoms of anxiety and depression and acknowledge them as common among people drinking above recommended safe limits. It could suggest resources that users may want to access for help, depending on their severity, for example their GP, their local Improving Access to Psychological Therapies (IAPT) service or other Internet-based interventions, such as Beating the Blues or Fear Fighter, both of which are advocated by NICE (NICE Technology Appraisal 97 2008). Alcohol misusers are often also smokers and other drug users (NICE Pathways 2011). Similarly, DYD could include a list of resources, such as the NHS Stop Smoking Service for people who want to address this health behaviour. The implications of adding this information on potential comorbidities would need to be carefully considered as it may encourage the user to focus on different aspects of their behaviour and direct them away from DYD. It may also overwhelm them when they have come to DYD to address their drinking and therefore discourage them from addressing any health behaviour. Where further help is signposted it should respect the individual's anonymity and accept their decision whether or not to access it.

### ***Potential barriers to implementing Internet-based interventions***

The Down Your Drink intervention website was designed to be made freely available online, where the general public could access it from a private and anonymous setting at their convenience. Implementation of the DYD website (making it available online) had occurred prior to its redevelopment and before undergoing evaluation in the trial, therefore implementation of the intervention post trial was a relatively simple process. The DYD website received a steady flow of registrants before, during and after the trial, with approximately 500 unique visitors per week at present, thus demonstrating the need for such an intervention. However, when an Internet-based intervention for any health behaviour is initially developed and evaluated, an implementation strategy should be integral to the process (Medical Research Council 2008) and include careful consideration of the potential barriers that may be faced. For example, the technical specifications of an Internet-based intervention will impact on how and where it is implemented on the web, such as the type of browser, database, and programming languages used, memory requirements for facilitation of interactive components, and compatibility with operating systems (Ritterband 2003). Another challenge when implementing an Internet-based intervention is attracting users to visit the website. The need for the intervention should be determined at the development stage, along with a strategy for reaching those in need. There are several techniques available for increasing traffic to websites, including 1) search engine optimisation – this increases the visibility of a website to a search engine, examples include sponsored links (such as Google Ads), or inserting meta-tags (information about the website contained within an HTML file, accessed by search engines), 2) links from other sites, especially popular ones, 3) advertisements in forums or on social networking websites. Other barriers to implementation which are likely to transfer to Internet-based interventions for all health behaviours include, cost, lack of consideration given to patient or staff characteristics when designing the intervention (e.g. health literacy, computer literacy, patient expectations), user concerns about confidentiality

of data, and lack of financial incentives for clinicians to use Internet-based interventions in practice (Brown et al. 2007). The latter of these potential barriers considers the implementation of Internet-based interventions in a particular setting. The DYD website was designed to help hazardous and harmful drinkers, and whilst some maybe seeking help online with their drinking, the majority will not be seeking any type of help. Studies of computer-based interventions included in the systematic review (Chapter 2) delivered the intervention to non-help seeking samples in a variety of settings including, university, the emergency department, the workplace, and to the general population. The potential barriers to implementing Internet-based interventions for alcohol misuse in these settings are beyond the scope of this thesis, but are worthy of future research.

### ***Reaching different populations - Down Your Drink in other settings***

The DYD trial attracted slightly more women than men (57%), a highly educated sample (52% degree level and above) drinking large amounts of alcohol (average 46 units per week). Although it is encouraging that the DYD trial recruited a large number of women, particularly when studies of brief interventions in primary care recruit mostly men (57% vs. 30%) (Kaner et al. 2007), it is important to consider ways of reaching more men when 33% men (compared with 16% women) are drinking hazardously or harmfully in England (The NHS Information Centre 2009). Despite the higher number of men recruited to brief intervention trials in primary care, men visit their GP 20% less than women (Office of National Statistics 2007), which therefore lowers the opportunity for screening and brief intervention. The workplace provides an ideal setting for accessing a range of professional men who are not seeking help with their drinking, and which is not dependent on whether they are ill (primary care, pharmacy), injured (emergency department), or at university.



The next trial involving the DYD website will be based in a large national company with 93,000 employees, around 78% of which are men (BT 2012). Building on the limitations of the initial DYD RCT, efforts will be made to reduce the impact of reactivity of assessment and social desirability bias. All employees will receive a health screening questionnaire, with questions on weight, height, smoking, diet, exercise and alcohol. Those scoring five or more on the AUDIT-C will be entered into the trial. Participants will then be randomised to a group that receives feedback on all health behaviours (intervention arm), or a group that receives feedback on all health behaviours except alcohol (comparator arm). The comparator group will receive alcohol-related feedback three months later in a wait-list design. Having received feedback that they are drinking above recommended safe limits, participants will be directed toward the Down Your Drink website for help to reduce their drinking. Participants will not be asked to complete the TOT-AL until follow-up to minimise reactivity of assessment. Unlike the e-help seekers in the original trial, participants in this workplace trial will be classified as non-help seekers, suggesting they will have less motivation to change their drinking – one explanation for the negative results of the DYD trial. Screening for a range of health behaviours rather than alcohol consumption alone may also limit the possibility of social desirability bias, where the participant is unaware of the exact aim of the trial. Like the DYD RCT reported in this thesis, this will be an online trial. It is therefore relatively low cost and, if the intervention is successful at reducing people's alcohol consumption, could potentially be implemented in occupational health departments nationwide.

### ***Future development of Internet-based interventions***

One of the key advantages of Internet-based self-help interventions is that they have the capacity for interactivity. This interactivity enables personalisation of the behaviour change techniques thought to comprise effective components of these interventions, such

as feedback on alcohol consumption, goal-setting and self-monitoring (Abraham & Michie 2008). The DYD intervention website included interactive 'e-tools', such as the Drinking Episode Diary, the Thinking Drinking Record, Blood Alcohol Level calculator, unit counter, and the alcohol and relationships feature. However, the capabilities of the Internet and the way in which people access it are constantly evolving. In 2011, almost half of people with a mobile phone used it to access the Internet (Dutton & Blank 2011). An iPhone application that allowed for entry of drinks into the Drinking Episode Diary, whilst out drinking, was suggested by a few DYD participants for future development of the website (Chapter 6). Such applications already exist from NHS Choices (a health information website from the NHS) and Drink Aware (a UK charity that provides information about alcohol consumption, funded by the alcohol industry). Another suggestion for future development was a forum, where participants wanted to read positive stories from people in similar situations to themselves (Chapter 6). One of the studies of an Internet-based intervention for the general population included in the systematic review included a moderated forum. Participants in this trial were found to visit the forum an average of 9 times, whilst visiting the core components of the Internet-based intervention an average of 23 times (Riper et al. 2009). The trial publications did not include information on the type of information posted in these forums, whether it was found to be helpful, or whether participants contributed to the discussions (Riper et al. 2009; Riper et al. 2008b). DYD participants interviewed in Chapter 6 expressed concern that a forum could in fact be detrimental to their attempts to reducing their drinking if people were reporting their inability to cut down. The value of including a forum as part of an Internet-based intervention is an important question for future research in this field.

Internet-based interventions need to be more than evidence-based. They need to compete visually and technically with the online resources currently available for alcohol misuse and other health behaviours. A major disadvantage of Internet-based interventions

is that they do not retain their users, thus suggesting they may not be used as intended, which is a concern as the components necessary for behaviour change may not be accessed (Christensen et al. 2006; Cunningham et al. 2009; Eysenbach 2005). DYD participants were found to access the intervention website an average of two times. Whilst there is no consensus on what constitutes compliance with an Internet-based intervention, and this will undoubtedly vary from intervention to intervention, there are certain features that may improve engagement and continued use, such as interactive behaviour change techniques, multimedia, quizzes, videos, social support by peers and professionals, updated content, and prompts to revisit the website (Brouwer et al. 2011). To date, only peer and professional support, contact via email and phone, and updated content are supported by evidence (Brouwer et al. 2011). The e-help seekers identified in this thesis should be viewed as health consumers, with access to an abundance of health-related information and peer support over the Internet. This provides competition for Internet-based interventions, where people are likely to draw on a range of resources for help (Potts 2006). Although the source of the information is thought to be an important quality criteria for users (Kerr et al. 2006), Internet-based interventions need to compete with other available resources, in terms of visual appeal and functionality, to achieve engagement and encourage revisits. One of the challenges in meeting this competition that has been noted in the literature is that e-health progresses faster than e-health researchers (Potts 2006). By the time an Internet-based intervention has been subjected to an effectiveness trial it is likely to look dated. In three years time, popular technology will have moved beyond iPhone applications and social networking to more advanced ways of communicating, such as the human graphical interface. Although Internet-based interventions need to compete with the technical capabilities of other resources, it is important that they retain their theoretical grounding and that these technological updates serve to support the content of the website, not replace it. Funding is needed to update and maintain these interventions beyond the trial or arrangements should be made for

their adoption by suitable bodies that have the funds to maintain them, such as NHS Choices. The funds needed to develop mobile phone applications, or to man a forum are not insubstantial and may be off-putting to potential funding bodies, but it is necessary that the impact of these features are evaluated before being disseminated to the general public.

## ***Conclusion***

This thesis has used different research designs to determine the effectiveness of Internet-based interventions for reducing alcohol intake, to investigate ways of improving online trial methodology for the evaluation of internet-based interventions related to outcome measurement and attrition, and to explore users' experiences of using an Internet-based alcohol misuse intervention. This empirical research has provided a unique contribution to the emerging field of Internet-based alcohol misuse interventions and online trial methodology, addressing many of the limitations of previous research. It has highlighted the need for more rigorous effectiveness data that addresses these methodological limitations and fills the current gaps in the literature. It also calls for further research to determine the varied need among this unique population of e-help seekers, leading to the development a range of interventions best suited to that need.

## Appendix 2. MEDLINE search strategy

### Computer-related terms:

#33 ((personal adj digital adj assistant) or pda) in ti,ab,kw  
#32 (surf\* near4 internet\*) in ti,ab,kw  
#31 (surf\* near4 web\*) in ti,ab,kw  
#30 (virtual adj reality) in ti,ab,kw  
#29 (consumer adj health adj informatic\*) in ti,ab,kw  
#28 ((e adj health) or e-health or (electronic adj health)) in ti,ab,kw  
#27 (interactive near ((health adj communicat\*) or televis\* or video\* or technolog\* or multimedia)) in ti,ab,kw  
#26 ((bulletin adj board\*) or bulletinboard\* or messageboard\* or (message adj board\*)) in ti,ab,kw  
#25 (blog\* or web-log\* or weblog\*) in ti,ab,kw  
#24 ((chat adj room\*) or chatroom\*) in ti,ab,kw  
#23 (online or on-line) in ti,ab,kw  
#22 ((internet adj based) or Internet-based) in ti,ab,kw  
#21 ((web adj based) or web-based) in ti,ab,kw  
#20 ((world adj wide adj web) or (world-wide-web) or www or (world-wide adj web) or (worldwide adj web) or website\*) in ti,ab,kw  
#19 ((electronic adj mail) or e-mail\* or email\*) in ti,ab,kw  
#18 ((mobile or cellular or cell) adj (phone\* or telephone\*)) in ti,ab,kw  
#17 ((CD adj ROM) or cd-rom or cdrom or (compact adj dis\*)) in ti,ab,kw  
#16 (decision adj (tree\* or aid\*)) in ti,ab,kw  
#15 (internet or (local adj area adj network\*)) in ti,ab,kw  
#14 (computer\* or microcomputer\* or laptop) in ti,ab,kw  
#13 explode "Software-" / all SUBHEADINGS in MIME,MJME,PT  
#12 explode "Computer-Graphics" / all SUBHEADINGS in MIME,MJME,PT  
#11 explode "Public-Health-Informatics" / all SUBHEADINGS in MIME,MJME,PT  
#10 explode "Computer-Assisted-Instruction" / all SUBHEADINGS in MIME,MJME,PT  
#9 explode "Audiovisual-Aids" / all SUBHEADINGS in MIME,MJME,PT  
#8 explode "Decision-Support-Techniques" / WITHOUT SUBHEADINGS in MIME,MJME,PT  
#7 explode "Medical-Informatics" / all SUBHEADINGS in MIME,MJME,PT  
#6 explode "Computer-Systems" / all SUBHEADINGS in MIME,MJME,PT

### Alcohol-related terms:

#5 (alcohol\* near (abuse or related disorder\* or drink\* or excessive or consum\* or intake or reduction or misuse\* or dependen\*)) in ti,ab,kw  
#4 ((heavy or hazardous or harmful or excessive or problem or binge or controlled) adj drink\*) in ti,ab,kw  
#3 explode "Alcoholic-Beverages" / all SUBHEADINGS in MIME,MJME,PT  
#2 explode "Alcohol-Drinking" / all SUBHEADINGS in MIME,MJME,PT  
#1 explode "Alcohol-Related-Disorders" / all SUBHEADINGS in MIME,MJME,PT

### Appendix 3. Conversion factors for grams per week

Study ID	Measure of total consumption	Conversion factor	Source of conversion	Other conversions
1. Barnett et al. 2007	Drinks / month	11.671(x12/52)	Miller 1991	No. of drinking days multiplied by Average no. drinks per drinking day
2. Bewick et al. 2008	Units / week	8	Miller 1991	N/A
3. Chiauzzi et al. 2005	Drinks / week	11.671	Miller 1991	SD estimated from CI before conversion factor applied
4. Donohue et al. 2004	Drinks / month	11.671(x12/52)	Miller 1991	Low risk and high risk groups combined (group determined by mean baseline alcohol consumption)
5. Dumas & Hannah 2008	Outcome not measured	N/A	N/A	N/A
6. Dumas & Haustveit 2008	Drinks / week	11.671	Miller 1991	N/A
7. Hedman 2007	Outcome not measured	N/A	N/A	N/A
8. Hester & Delaney 1997	Drinks/ week	11.832	Hester 1997	N/A
9. Hester et al. 2005	Drinks / day	11.832(x7)	Hester 1997	Anti-log ( $=10^{(x)}$ ) taken before conversion factor applied
10. Hunt 2004	SD missing	N/A	N/A	N/A
11. Kypri et al. 2004b	Total consumption (number of drinks in last 2 weeks)	10(/2)	Kypri 2008	Mean estimated from median, sd estimated using range.
12. Kypri & McAnally 2005	Outcome not measured	N/A	N/A	N/A
13. Kypri et al. 2008	Total consumption (number of drinks in last 2 weeks)	10(/2)	Kypri 2008	Single- and multi dose e-SBI combined. Mean estimated from median, sd estimated using range.
14. Lau-Barraco & Dunn 2008	Drinks / week	11.671	Miller 1991	N/A
15. Lewis et al. 2007	Drinks / week	11.671	Miller 1991	SD estimated from SE (for 3 groups) and 2 intervention groups combined before conversion factor applied.
16. Lewis & Neighbors 2007	Drinks / week	11.671	Miller 1991	SD estimated from SE (for 3 groups), male and female means and SD combined for 3 intervention groups, and 2 intervention groups combined before conversion factor applied.

17. Matano et al. 2007	Outcome not measured	N/A	N/A	N/A
18. Neighbors et al. 2004	Drinks / week	11.671	Miller 1991	SD estimated from SE before conversion factor applied
19. Neighbors et al. 2006	Drinks / week	11.671	Miller 1991	N/A
20. Neumann et al. 2006	Grams / day	x7	N/A	Mean estimated from median, sd estimated using range.
21. Paschall et al. 2006	Outcome not measured	N/A	N/A	N/A
22. Riper et al. 2008b	Weekly alcohol consumption	10	Riper 2008b	SD estimated from SE (of difference) before conversion factor applied
23. Walters et al. 2007	Drinks / week	11.671	Miller 1991	SD estimated from CI before conversion factor applied
24. Weitzel et al. 2007	Alcohol consumption (total drinks during study period = 2 weeks)	11.671(/2)	Miller 1991	SD estimated from P

#### Appendix 4. Conversion factors for binge frequency per week

Study ID	Measure of binge frequency	Conversion factor	Other conversions
1. Barnett et al. 2007	Number of heavy drinking days (past month)	x12/52	N/A
2. Bewick et al. 2008	Outcome not measured	N/A	N/A
3. Chiauuzzi et al. 2005	Binge drinking days / wk	N/A	SD estimated from CI
4. Donohue et al. 2004	Outcome not measured	N/A	N/A
5. Doumas & Hannah 2008	Outcome not measured	N/A	N/A
6. Doumas & Haustveit 2008	Outcome not measured	N/A	N/A
7. Hedman 2007	30 day frequency of binge drinking (14 day also available)	x12/52	N/A
8. Hester & Delaney 1997	Outcome not measured	N/A	N/A
9. Hester et al. 2005	Outcome not measured	N/A	N/A
10. Hunt 2004	Proportion of binge days per month	N/A	N/A
11. Kypri et al. 2004b	Frequency of episodic heavy drinking (past 2 weeks)	/2	N/A
12. Kypri & McAnally 2005	Outcome not measured	N/A	N/A
13. Kypri et al. 2008	Frequency of episodic heavy drinking (past 2 weeks)	/2	Single- and multi dose e-SBI combined
14. Lau-Barraco & Dunn 2008	Heavy episodic drinking frequency (days / wk)	N/A	N/A
15. Lewis et al. 2007	Outcome not measured	N/A	N/A
16. Lewis & Neighbors 2007	Outcome not measured	N/A	N/A
17. Matano et al. 2007	Outcome not measured	N/A	N/A
18. Neighbors et al. 2004	Outcome not measured	N/A	N/A
19. Neighbors et al. 2006	Outcome not measured	N/A	N/A
20. Neumann et al. 2006	Outcome not measured	N/A	N/A
21. Paschall et al. 2006	Frequency of having five or more drinks in past 30 days - measured as a categorical variable	N/A	N/A
22. Riper et al. 2008b	Outcome not measured	N/A	N/A
23. Walters et al. 2007	Outcome not measured	N/A	N/A
24. Weitzel et al. 2007	Outcome not measured	N/A	N/A



## Appendix 5. Evidence of skewed distributions

Study ID	Skew - g/week	Skew - binge/week	Acknowledgement of skew/ suitable analyses undertaken	Raw data
1. Barnett et al. 2007	intvn=2.50 cont=2.28	intvn=0.83 cont=0.82	No	g/week: untransformed - no evidence of skew; binge/week: assume untransformed.
2. Bewick et al. 2008	intvn=0.89 cont=0.80	Outcome not measured	Yes	Untransformed (data were transformed for analysis)
3. Chiauzzi et al. 2005	intvn=0.90 cont=1.00	intvn=0.79 cont=1.12	Yes (some data were log-transformed, but not these outcomes)	Untransformed (not considered necessary to transform)
4. Donohue et al. 2004	intvn=0.71 cont=0.72	Outcome not measured	No	Assume untransformed
5. Dumas & Hannah 2008	Outcome not measured	Outcome not measured	N/A	N/A
6. Dumas & Haustveit 2008	intvn=0.77 cont=0.55	Outcome not measured	No (extreme cases excluded from analyses - more than 3 standard deviations from the mean)	Assume untransformed
6. Hedman 2007	Outcome not measured	intvn=1.25 cont=1.28	No	Assume untransformed
7. Hester & Delaney 1997	intvn=1.48 cont=1.42	Outcome not measured	No	Assume untransformed
8. Hester et al. 2005	intvn=1.43 cont=2.64	Outcome not measured	Yes	Anti-log taken from transformed data. Untransformed data also available
9. Hunt 2004	Missing SDs	Missing SDs	N/A	N/A
10. Kypri et al. 2004b	intvn=1.55 cont=1.17	intvn=1.15 cont=0.86	Yes	Medians and range. Ratio of geometric means available
11. Kypri & McAnally 2005	Outcome not measured	Outcome not measured	N/A	N/A
12. Kypri et al. 2008	intvn=1.07 cont=1.10	intvn=0.63 cont=0.84	Yes	Medians and range. Rate ratio available
13. Lau-Barraco & Dunn 2008	MAC: intvn=0.96 cont=1.09 AC: intvn=0.96 cont=1.16	MAC: intvn=1.05 cont=1.22 AC: intvn=1.05 cont=1.09	No	Assume untransformed
14. Lewis et al. 2007	intvn=1.23 cont=1.59	Outcome not measured	No	Assume untransformed
15. Lewis & Neighbors 2007	intvn=1.85 cont=2.44	Outcome not measured	Yes (no extreme univariate departures from normality were evident for any variable)	Untransformed - no evidence of skew
17. Matano et	Outcome not	Outcome not	N/A	N/A

al. 2007	measured	measured		
18. Neighbors et al. 2004	intvn=0.97 cont=1.06	Outcome not measured	Yes (variable distributions were examined for univariate and multivariate non-normality. Although several variables exhibited some departure from normality, none of these departures were extreme, as defined in the SEM literature)	Untransformed - no evidence of skew
19. Neighbors et al. 2006	intvn=1.17 cont=1.08	Outcome not measured	No	Assume untransformed
20. Neumann et al. 2006	Medians - not included in meta-analysis	Outcome not measured	Yes	Medians and range.
21. Paschall et al. 2006	Outcome not measured	Outcome not measured	N/A	N/A
22. Riper et al. 2008b	intvn=0.93 cont=1.30	Outcome not measured	No	Assume untransformed
23. Walters et al. 2007	intvn=0.46 cont=0.53	Outcome not measured	Yes	Log-transformed and back-transformed.
24. Weitzel et al. 2007	intvn=0.76 cont=0.84	Outcome not measured	No	Assume untransformed

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